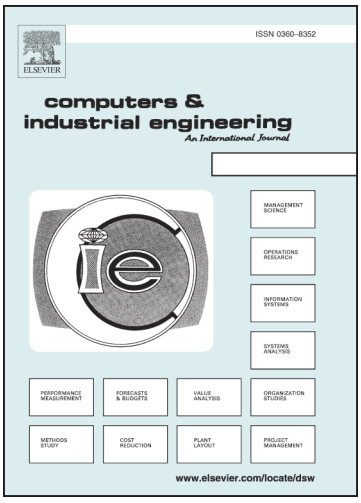

An activity-based defect management framework for product development

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Abstract: As competition intensifies, development of complicated hardware products and the decrease in development cycle lead to increasing design defect risk in hardware products, resulting in all kinds of problems such as unsafe product, product development failure and so on. Therefore, it is important to manage design defect during all stages of product development to improve product design quality and product development success rate. Factors influencing design defects injection vary according to the different attributes of a product development, including the product complexity, the experience of the developers, the development cycle and tool. The most significant challenge in design defect management is to identify design activities that are likely to cause defects. This paper proposes a design defect management framework based on design activities that assess and identify design defects. First, the product development process is decomposed by using a work breakdown structure (WBS) to obtain

design activities. Subsequently, a Bayesian network is adapted to construct defect assessment model using design activities as network nodes. Finally, the defect control activities such as review, verification, and validation are used to identify design defect. The proposed risk management framework enables an product development to be focused on the key defect activities in which the most serious defect risk exists and provides a more effective way to assess, identify defect risk along the product development cycle. A case study on medical syringes is presented to validate the capability of the proposed approach in providing low residual defect in delivered products.

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An activity-based defect management framework for product development

Abstract

As competition intensifies, development of complicated hardware products and the decrease in development cycle lead to increasing design defect risk in hardware products, resulting in all kinds of problems such as unsafe product, product development failure and so on. Therefore, it is important to manage design defect during all stages of product development to improve product design quality and product development success rate. Factors influencing design defects injection vary according to the different attributes of a product development, including the product complexity, the experience of the developers, the development cycle and tool. The most significant challenge in design defect management is to identify design activities that are likely to cause defects. This paper proposes a design defect management framework based on design activities that assess and identify design defects. First, the product development process is decomposed by using a work breakdown structure (WBS) to obtain design activities. Subsequently, a Bayesian network is adapted to construct defect assessment model using design activities as network nodes. Finally, the defect control activities such as review, verification, and validation are used to identify design defect. The proposed risk management framework enables an product development to be focused on the key defect activities in which the most serious defect risk exists and provides a more effective way to

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1 Introduction

In today's environment, intense competition forces manufacturing firms to develop new products at an increasingly rapid pace to gain premium pricing and higher sales volume. This phenomenon is especially seen in hardware products. In quality engineering fields, tangible products with specific shape and separability are called hardware products (also called products), which are the most widely used in the industry and life field. Typical examples of tangible products include electronic equipment, automotive, medical devices, and DVD recorders, etc. Faster market development leads to higher design defect risk in products. Given the continuously growing possibilities provided by technologies and their wider range of applications, products are becoming more and more complicated to meet customer's various demands, thus increasing the risks of product design defect. An adequate defect risk management is indispensable to avoid or reduces cost and time for rework of design activities as well as to achieve an delivered quality level.

Accidents caused by product design defects can lead to devastating consequences. For example, failure of communication signals led to the Wenzhou Train high speed crash disaster in China on July 23, 2011, in which 40 people were killed and at least 192 were injured. The failure of equipment in this disaster was caused directly by the design defect of the electrical

control system.

Design defects determine whether a company will survive or fail. Enterprises suffer from enormous economic losses as well as reputation crisis because of design defects. Managing product defect throughout the development process is thus becoming crucially important, as it is a means to improve a product's reliability and security.

The management of design defect consists of defect identification, defect removal, and defect control and so on. Product design defect identification is especially crucial and indispensable for design defect management. Moll pointed that defects should be identified and removed as early as possible. Otherwise, defects may be propagated and dispersed to the subsequent phases of product development. (Moll et al., 2004). A case of 68 projects is given in Ebert's study, where early defect detection activities decreased the residual defects to 70%. (Ebert et al., 2001). Jacobs et al. also found that an increased likelihood of injection as well as propagation of defect results to higher amounts of defect in the final product (Jacobs et al., 2005). All kinds of industrial product regulations which focus on the identification of product defects have been established by a nation. But there are still many problems such as backward regulations, insufficient attention to the design defects which exist in the product quality management system.

Some research pays more attention to design defects of the specific product. Li pointed out that violent wind, drastic turbulence, and sudden change of wind direction are major factors of wind turbine failures by collecting historical data of wind turbine failures (Li et al., 2013). Fan proposed basic theory system for fault tolerance and fault rectification design of electro mechanical products (Fan et al., 2007). Su identified and located assembly design

defect of mechanical products by analysis of cumulative deviation (Su et al.,2012). LU developed a prototype system of dynamic relating assembly verification to monitor the influence of design change on constrain relationship synchronously and check the design defect which violated the assembly constrain relationships dynamically (LU et al.,2012).Though these studies provide valuable information about defect identification, these studies are mainly concerned with specific products.

With the development of mobile internet, social media and cloud technologies, more and more people express their opinions about products online. These user's feedbacks could be easily collected. So some studies have proposed product design defect identification method based on user online review experience and sentiment analysis. Lin pointed out that testing network products in a beta site is good for finding design defects of top product design (Lin et al.,2010) .Zhang song proposed a framework of phones defect discovery from social media. The framework includes collecting phones defect data and defect clustering analysis and so on (Zhang et al.,2016). Abrahams employ text mining on online discussion forums used by vehicle enthusiasts to find, categorize, and prioritize vehicle defects (Abrahams et al.,2012). He further proposed an integrated text analytic framework for product defect discovery (Abrahams et al.,2015). Law utilized cross-domain sentiment techniques for the discovery of the defect in dishwashers (Law et al.,2015). Though these researches can be highly beneficial to improving product quality management methods. These studies are belonging to post action control.

Various approaches to detect software defects, such as the traditional statistical approach, software metrics models are available (Fenton and Neil, 1999). Fenton proposed that causal

model such as Bayesian are needed for more accurate software defect prediction (Fenton et al., 2007). Park introduced a design methodology of polynomial function-based neural network predictors for detection of the software defect (Park et al., 2013). Van presented ideas of defect detection-oriented lifecycle modeling in complicated product development (Van Moll et al., 2002). On the basis of a case study, he found that transitions among the constituent sub-projects are particularly defect-sensitive. In addition, according to his study, a defect detection-driven construction of a project-specific lifecycle could reduce the amount of residual defects. A meta-model is proposed to describe design patterns. Descriptions are exploited to infer sets of detection and transformation rules, which could implement software design defect identification and code correction (Gueheneuc and Albin-Amiot, 2001). In view of "design for verification" principle, Markosian proposed a program model checker for flight controlling systems in National Aeronautics and Space Administration (NASA) for detecting subtle software defect (Markosian et al., 2007). Several methods on soft design defect are applied in the research of hardware product design defect. However, these methods are not commonly used in practice.

The above researches put forward the method of identifying the design defects from all aspects, but did not consider the formation process of design defect. A product development process is complex which involves a series of phases and activities. In every activity, many factors exist that will influence the ability of the activity to meet its requirements completely. That is, product design defects may be injected in every activity of development. Hopefully, some defects are identified by the Revision& Verification & Validation activities (called defect identification activities) performed. The identified defects are subsequently removed

through all product development stages. However, too much defect identification activity will increase the cost of product development and even extend the product development cycle. Furthermore, in most cases, the decision of defect management is generally made in an intuitive manner. Thus, we seek to explore the following issue in this paper: the problems of when or where to identify design defects must be solved. Then serious attention should be paid to activities with a higher occurrence probability of defect.

In the present study, the study about design defect identification from the viewpoint of the design defect formation process is still empty and defect management based on the defect identification is also lacking. Based on our previous study about the relationship between defect propagation and design activities (Zheng et al., 2007), this paper suggests a new activity-based defect management framework (DMF) as shown in Fig.1. The entire structure of the DMF consists of five steps: (1) construction of product development process breakdown structure. (2) defect risk assessment (3) defect identification (4) defect removal (5) defect re-assessed. In phase (1), the work process breakdown is applied to get product development activities. In phase (2), the Bayesian topology structure is firstly constructed by analyzing the sequence of design activities and then activity node probabilities are determined, incorporating empirical data and expert judgement. The critical defect activities are determined according to the probability of defect occurrence. In phase (3), the appropriate approach (review or verify or validate) is selected to identify the defects where the higher occurrence probability of defect. In Phase (4), the identified defect is removed and defect re-assessed model is constructed in phase (5).

The rest of the paper is organized as follows. In Section2, work breakdown structure is

adapted to get design activities. Section 3 constructs an activity-based defect assessment model using Bayesian networks. Section 4 illustrates defect identification activities. A case is presented in Section 5 to demonstrate the effectiveness of this proposed approach. Finally, conclusions and issues for further research are presented.

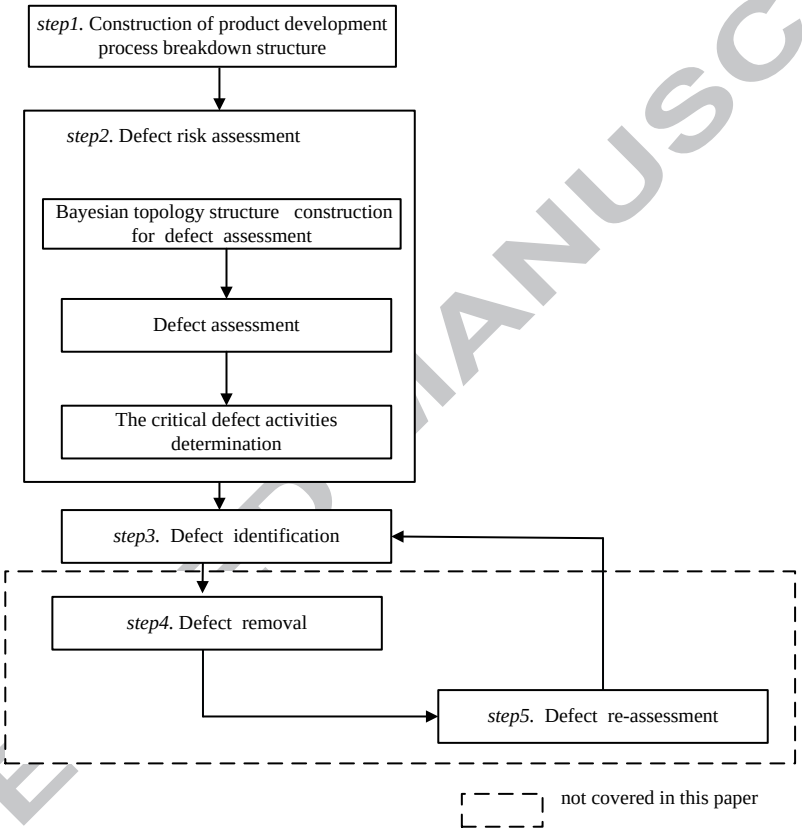

Fig. 1. The entire structure of the product design defect management framework

2. Design activities

The concept and application of the WBS for project management were first proposed by the US Department of Defense and NASA in 1962 (Morris, 1997). WBS is originally defined as a product-oriented family tree consisting of hardware, services, and data, which result from project engineering efforts during development (García-Fornieles et al., 2003). However, with the application study of WBS in different fields, the concept of WBS is defined differently in

literature. Thus, WBS also can be extended to other forms, such as the product breakdown structure, functional work breakdown structure, and relational work breakdown structure, thus obtaining a multidimensional approach (Hashemi Golpayegani and Emamizadeh, 2007). The WBS provides an effective way of decomposing the task required to achieve the final project deliverable, which is done in an analytic hierarchical fashion. By doing so, the complexity of the product development process is reduced because the product development tasks are decomposed until design activities reach a manageable size.

The product development process usually consists of numerous activities where the activities may be dependent or interdependent with each other. Parallel, sequential, and coupling are three main sequencing relationships between activities in a PD process. Each activity is open to the injection of defects and the relationship between activities will affect the defect propagation from one activity to another. Parallel structure has no relation to defect propagation, whereas the structures of sequential and coupling will propagate defect between activities. The work breakdown structure for product development process is called Process Breakdown Structure (PBS) which is an activity-oriented tree structure. As we know, a product development process is commonly comprised of four stages: product planning stage, concept design stage, detail design stage, and process design stage. Fig.1 shows some activities of each stage.

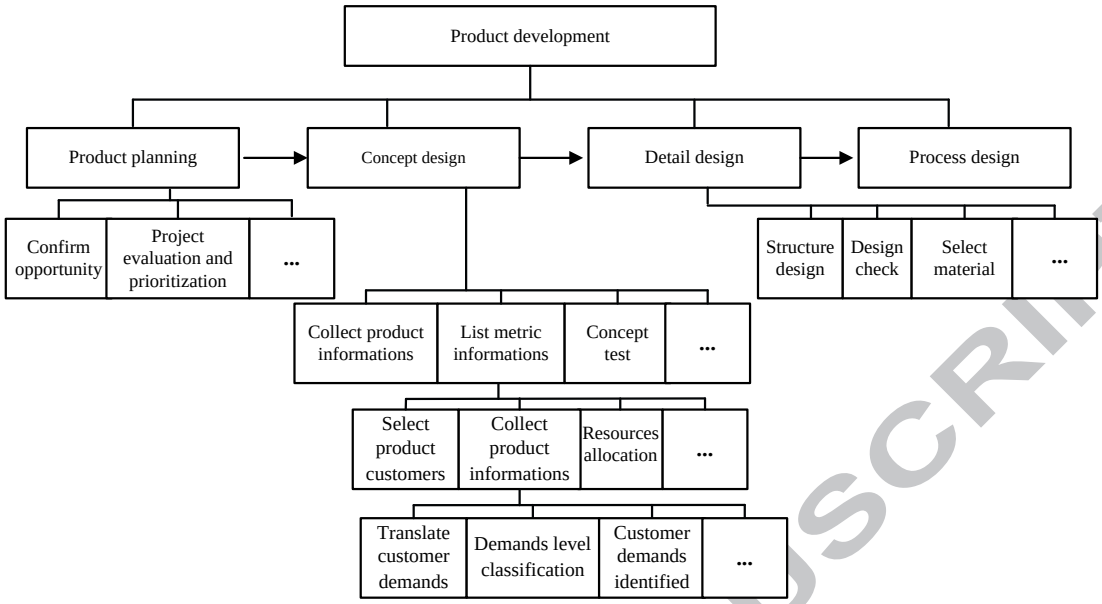

Fig.2 Development process breakdown structure

As defect assessment is a crucial process for design defect identification, the next sections of this paper focus on constructing a defect assessment model to determine the critical activities with higher likelihood of defect occurrence.

3 Defect risk assessment using Bayesian network

The construction of an effective product design defect risk assessment model is one of the key challenges to identify the critical defect activities with a higher occurrence probability of defect. A Bayesian network is a powerful tool for decision support systems with uncertainty (Lee et al., 2009). Thus, we regard the Bayesian network as a desirable means for this work.

3.1 Bayesian networks

Bayesian networks, also called Bayesian belief networks, are based on graphs and probability theories and are a powerful modeling technique for uncertain knowledge representation and effectively reasoning (Jie et al., 2002). Bayesian networks are generally used to describe the probabilistic relationships among the variables. Bayesian networks are widely applied to various fields, such as semantic webs (Chen and Chuang, 2008), decision

support (Mussi, 2004), and risk assessment (Hu et al., 2013). A Bayesian belief network includes qualitative and quantitative parts. The qualitative part, in the form of a directed acyclic graph (DAG), consists of a set of nodes of uncertain variables, in which the nodes represent a finite set of states and the edges of nodes represent the causalities between variables. Here, design activities (are regarded as the nodes of Bayesian networks. The defect nodes of customer demand activities are given in Fig 3. The quantitative part, which consists of a set of conditional probability table, describes the conditional probability distributions among the activity nodes and is presented in Table 1, the values of the quantitative part are obtained from empirical data or given by expert judgments.

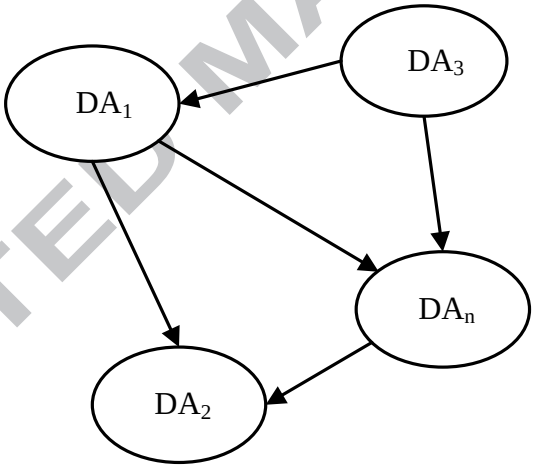

Fig. 3. Sample of Bayesian Belief Networks

Table1
Example of conditional probability table (CPT) for DA_n

	DA_1	**State 1**		**State 2**	
	DA_3	**State 1**	**State 2**	**State 1**	**State 2**
DA_n	State 1	0.9	0.2	0.5	0.3
	State 2	0.1	0.8	0.5	0.7

3.2 Assessment of defect occurrence using Bayesian networks

The chain rule states that a Bayesian network is a representation of the joint distribution of all the variables represented in the DAG. The marginal and conditional probabilities can be

calculated for each node in the network.

If the defect of design activities is a universe of variables which is given as follows:

$$DA = \{DA_1, DA_2, ..., DA_n\} \quad (1)$$

The joint probability of DA is then expressed as:

$$P(DA) = \prod_{i=1}^{n\ 1} P(DA_i \left| DA_{i+1,...,} DA_n \right.) \quad (2)$$

From the joint probability distribution $P(DA)$, various marginal and conditional probabilities $P(DA_i), P\left(DA_i \left| DA_j \right.\right)$ or $P\left(DA_i \left| DA \right.\right)$ can be calculated e.g.

For a set of discrete variables, DA_i represents the likelihood distribution of each activity over the states of defect occurrence. Under the condition that the design defect occurrence is known, the probability of defect occurrence for each design activity can be calculated.

$$P\left(DA_i | DA\right) = \frac{P\left(DA \left| DA_i \right.\right) P\left(DA_i\right)}{\sum_{j=1}^{n} P\left(DA \left| DA_j \right.\right) P\left(DA_j\right)} \quad (3)$$

Critical defect activity refers to the activity with a higher occurrence probability of defect.

4 Defect identification

Design review, verification, and validation (RVV) are three basic quality control activities in the product development process that focus on ensuring that products are designed and delivered to satisfy customer requirements in the best way possible (Ebert et al., 2001， Jacob et al.,2012). Likewise, RVV activities have, proven to be the most valuable technique in defect identification and prevention. According to the definitions arising from ISO9000, the design review is an important mechanism to ensure that the design output meets the requirements of the design input, which is applied to systematically check the results formatted in the design process. Verification and validation are the approach that is applied to

confirm whether a product meets its respective specifications and accomplishes its intended purpose. Generally, design verification is a quality control activity that is utilized to evaluate whether or not design result is in accordance with specifications or regulations provided at the beginning of a product development phase ((Maropoulos and Ceglarek, 2010). However, design validation is a quality assurance activity based on objective evidence which provides a high degree of assurance that a product fulfills its desired application requirements. Given that design RVV is broadly defined in the ISO, it has been defined in various ways in different fields, which do not necessarily comply with standard definitions (Allen et al., 2005). In the view of ISO standards as well as general hardware product development procedure, each defect requires a specific method, as shown in Table 2. Furthermore, selecting an appropriate defect identification activity on various stages and determining the level of products in the system hierarchy are needed during the development of various types of products. Sometimes, selecting verification activities is sufficient enough to identify the design defect. However, in most cases, a design review combined with verification and validation should be selected to effectively identify the design defect.

The following problems still exist in the present product development for defect RVV:

(1) Few robust RVV methods are available to identify design defects during the product development stages;

(2) The complexity of products makes defect verification and validation even more difficult to apply as a part of the design process.

The fundamental verification activities generally include inspection, analysis, demonstration, and test. Take the testing process for example. Testing-related problems,

mainly stem from technical aspects, such as test tools, incomplete test coverage, or inadequate test conditions. Other causes may exist in the testing process, such as test environments, test management, and change control. In addition, a more rigorous test can increase the number and proportion of defect found during the test process, thus lowering the number of latent defect in the delivered product. Therefore, much attention should be paid to the research on defect control activities to minimize defect injection and to maximize defect identification.

Table 2

Relationships between defect identification activities and defect types

Defect Identification Activities	Basic Activities	Defection Type
Defect review	Meeting, Circulate etc.	Function defect, Structure defect
Defect verification	Inspection, Analysis, Demonstration, Test etc.	Structure defect, Performance defect and Process defect
Defect validation	Try, Simulate etc.	Function defect

5 Case study

The proposed method has been validated with a case studying the design defect of a medical syringe, which is a common medical apparatus. The company is an original design manufacturer with high-end medical instrument product. Currently, the company attempts to design and develop a medical syringe with durability and precise measurement. Investigations reveal that the design defects of the existing syringe are as follows:

(1) Given the instability of the syringe dial, the disc's pointer may be locked, which results in wrong pressure indicator and thus affect the operation;

(2) The cap of the syringe needle can be easily lost, making it susceptible to infection;

(3) Disinfecting the syringe is difficult;

(4) The graduation of the syringe is blurry, and the number cannot be read clearly and correctly;

(5) Syringes are easily damaged, thus causing air leakage;

(6) The inner vessel of the syringe easily becomes moldy.

To identify the above defects of the medical syringe, defect assessment is executed concurrently with concept development activities to guide the product designers in determining the activities that need to be identified.

Step1: Concept design activity decomposition

The concept design process of a syringe contains many tasks that can be further divided into 24 activities. The activities can be represented by using PBS. The result is shown in Table 3.

Table 3
Concept design activities of a medical syringe

Design activities	Symbol	Design activities	Symbol
Select Product Customers	A_1	Sort out Problems	A_{13}
Collect Product Information	A_2	Internal Search	A_{14}
Translate Customer Demands	A_3	External Search	A_{15}
Demands Level Classification	A_4	Seeking Action Principle Portfolio	A_{16}
Customer Demands Identified	A_5	Reflection Solutions Process	A_{17}
List Metric Informations	A_6	Generate Concept Program	A_{18}
Collect Benchmarking Informations	A_7	The Concept Coarse Sieve	A_{19}
Determine The Index Range	A_8	Concept Evaluation	A_{20}
List Performance Index	A_9	Concept Sort	A_{21}
Refine Performance Index	A_{10}	Concept Test	A_{22}
Determine Indicators	A_{11}	Determine Concept Scheme	A_{23}

Function Decomposition	A_{12}	Review Concept Scheme	A_{24}

Step 2: Defect risk assessment

The whole defect assessment process of concept design activities for medical syringe consists of three steps. The first step is the construction of a Bayesian topology structure for defect assessment. An initial Bayesian topology structure model for syringe concept design reflects the defect propagation from one design activity to another on the basis of expert knowledge, history data, and relationship analysis between activities (Fig. 4). The information propagation in coupling activities is generally closer, and coupling activities are usually integrated as a whole. Fig. 4 shows that activities 14, 15, and 16 are integrated as a single activity and that DA and $DA^{'}$ denote different meanings, respectively. For example, DA_2 is the defect from the activity of Collect Product Information. However, $DA_2^{'}$ denotes defect from the activity of Collect Ipropagationand defect propogation fr.the former activity DA_1.

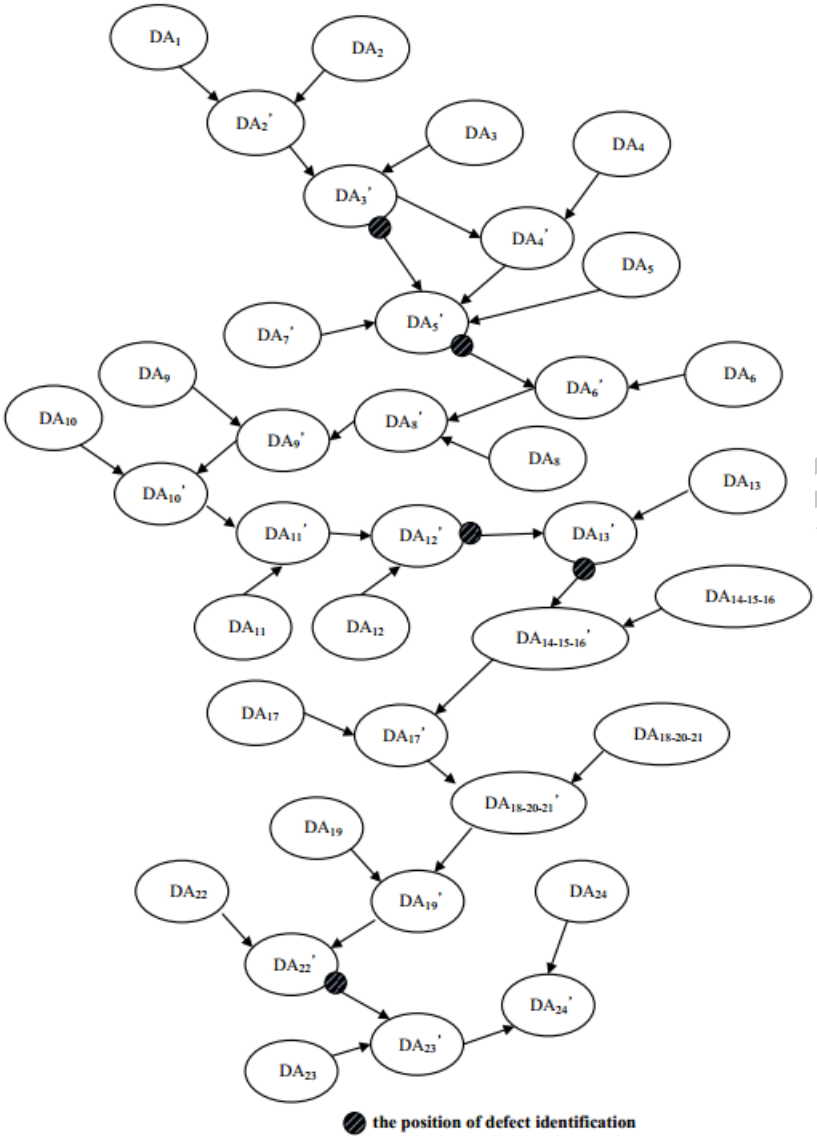

Fig. 4. An initial Bayesian topology structure model for syringe concept design

The second step of syringe defect assessment is the determination of the prior probabilities for root nodes and the conditional probabilities for non-root nodes in BN. The design activities in the Bayesian network model have two states, namely, order and disorder, which are represented as and $X = 0$, respectively. The occurrence probabilities of the product design defect caused by each design activity are described by the prior probability of the root node, which represents the characters of a specific alternative. Thus, these probabilities may vary according to different alternatives, even if such alternatives belong to the same company.

By contrast, conditional probabilities describe the defect effect from design activities by using a design defect on other design activities. Conditional probabilities also reflect the company's strategies and objectives on product design and analysis, which may vary with different companies but remain the same for the same company. The above node probabilities can be obtained by a pairwise comparison approach, and their values can be determined by experts from a design company. To obtain the prior probability of the root node, experts from the medical syringe design department first analyzed the defect factors of each design activity and obtained the weight of each defect factor by using the analytic hierarchy process. Table 4 shows the factors and weights for the activity of customer demands identified. The probability of defect occurrence in each design activity is expressed as follows:

P_j is the probability of defect occurrence in each design activity, w_i is the weight for each affecting factor of defect occurrence, and p_i is the probability of defect occurrence caused by the affecting factor.

By referring to the methods in related literature (e.g., Chin et al., 2009), we can obtain the conditional probabilities of the non-root node (Table 5). However, we only list parts of the data in this study. , DA_7', and DA_5 represent the condition node values (Table 6). $P(DA_5'=0)$ and $P(DA_5'=1)$ are the probabilities of defect non-occurrence and defect occurrence, respectively.

Table 4
Factors and weight of Customer Demands Identified

Design activity	Defect factor	Weight
	Professional knowledge	0.3124
	The processed data	0.3057
A_5	Organizational mode	0.0847

	Environment	0.0768
	Information	0.1450
	Check method	0.0754

Table 5

Probability of defect occurrence in each design activity

Defect in each activity	$X=0$	$X=1$
DA_1	0.950	0.050
DA_2	0.875	0.125
DA_3	0.975	0.025
DA_4	0.925	0.075
DA_5	0.935	0.065
DA_6	0.895	0.105
DA_7	0.887	0.113
DA_8	0.943	0.057
DA_9	0.954	0.046
DA_{10}	0.898	0.102
DA_{11}	0.924	0.076
DA_{12}	0.945	0.056
DA_{13}	0.936	0.064
$DA_{14\text{-}15\text{-}16}$	0.948	0.052
DA_{17}	0.941	0.059
$DA_{18\text{-}20\text{-}21}$	0.927	0.072
DA_{19}	0.946	0.054
DA_{20}	0.938	0.062
DA_{21}	0.885	0.115
DA_{22}	0.912	0.088
DA_{23}	0.943	0.057
DA_{24}	0.945	0.055

Table 6

CPT of Customer demands identified identification

DA_4'	DA_7'	DA_5	$P(DA_5'=0)$	$P(DA_5'=1)$
0	0	0	0.372	0.628
0	0	1	0.658	0.342
0	1	0	0.713	0.287
1	0	0	0.732	0.268
1	1	0	0.837	0.163
1	0	1	0.825	0.175
0	1	1	0.822	0.178

1	1	1	0.918	0.082

After the above probabilities are determined, the inference can be performed to determine the probability of defect occurrence in each activity of the design work (Fig.5). Seen from Fig.5, the probabilities of these activities, such as A_5, A_{12}, A_{13}, and A_{22}, are higher; thus, we can infer that these activities have a significant effect on the design defect of the product. The probability of defect occurrence is only 3.2% at the Determine Concept Scheme stage. The defect occurrence is a small probability event (when the probability of defect occurrence is less than 5%, a design defect is unlikely to occur). Thus, we assumed that a defect would not occur at this stage. Fig. 4 shows that the likelihood of defect occurrence in these activities is much larger, i.e., these activities that are likely to cause defects. Thus, design defect identification should be implemented after the above design activities (Fig.5).

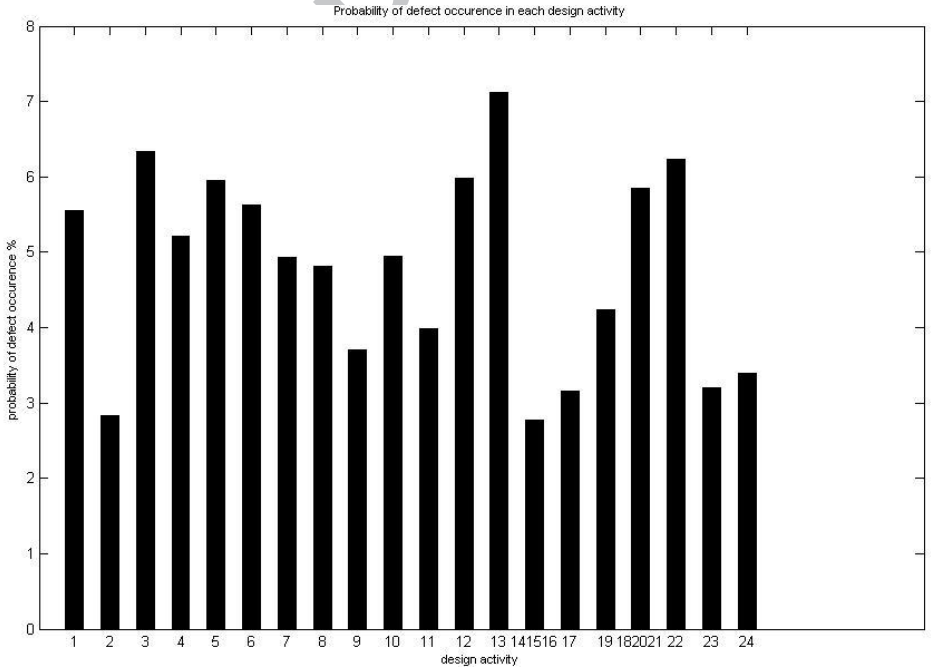

Fig. 5. The probability distribution of defect occurrence at the syringe concept design stage

Step 3：Defect identification

On the basis of the above mentioned information, we can implement defect identification by using methods such as review, verification, and validation. We use the activity of Concept

Test as an example to illustrate the identification process. Test goals must be specified first, and test specifications created on the basis of functional clusters of requirements should be clear and distinct. Explicit deliberations have been conducted on the test approaches described in the test report. We invite different customers and sales staff to review the concept test. Communications are conducted continuously to identify the springe function defect fully. According to customer feedback, we identify defect factors, such as insufficient knowledge and poor understanding of the product. Design change is accompanied by defect correction measures when adapting to the design process. Defects in design activities are then re-assessed. This process is repeated until the probabilities of defect occurrence are limited to a specified value.

The likelihood of defect occurrence in the activity of Sort Out Problems is the highest and may be more sensitive to defect injection than other activities (Fig. 5). Sort Out Problems has the most number of uncertain factors, and information is processed frequently. However, defect injection depends on the product and the environment. Defect not identified in the concept design stage tends to disperse and propagate further into the initial design, detail design, and process design, thus requiring more effort to solve. Therefore, adequate defect identification measures should apply to the key activities with higher defect risk. That is, a certain defect would have been identified earlier or have been prevented from being injected. Defect identification is the first step in the defect management process, in which latent defects associated with product development are identified. Once the defects during product development have been identified and analyzed, appropriate defect response measures must be adopted to cope with the defect. The defects in the design activities are then reassessed.

The treatment measures for each defect are based on the nature and effect of the defect to remove defects as much as possible. Owing to the randomness of defect occurrence, the defect management cannot eliminate all risks, but can lower the number of design defect to some extent. Applying these defect management approaches can prevent the propagation of design defects and eventually result in fewer defects in the delivered products.

6 Conclusion and discussion

Hardware product design defect management, one of the main subjects of product quality management, aims to assess, identify, and correct defects during the product development process. It is a critical and indispensable step to recognize possible defect injection activities for defect management. In this paper, an activity-based defect assessment and defect identification frame for defect management is presented to assist the product development manager to find the critical activities causing design defects. WBS is used to decompose the development process into design activities. A Bayesian network is applied to construct defect assessment model to evaluate the probability of defect occurrence in each activity. By detecting the suspect activities, identification and necessary corrective activities can be taken to prevent the design defects from occurring.

This article is aimed at identifying the critical defect activities that may injure defect. The limitations of this study were the reliance on an expert survey to construct the Bayesian defect assessment model and the consequent requirement for a great effort in data collection. Nevertheless, the outcome of this study already already provides sufficient information to help regulators to devise activities management strategies for lowering residual defects in products develop process. It may create

awareness in organizations to reconsider policies regarding the development and Verification & Validation.

Eventually, we determinate the critical defect activities. Therefore, we can perform defect management including design review, design verification and defect validation and so on. Future research will aim at finding the critical defect factors impact on defect activities and determining the degree of influence of those factors, to reach our ultimate goal –defect management strategies for reducing the number of residual defects.

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Fig. 1. The entire structure of the product design defect management framework

Fig. 2. Development process breakdown structure

Fig. 3. Sample of Bayesian Belief Networks

Fig. 4. An initial Bayesian topology structure model for syringe concept design

Fig. 5. The probability distribution of defect occurrence at the syringe concept design stage

Table1 Example of conditional probability table (CPT) for DA_n

Table 2 Relationships between defect identification activities and defect types

Table 3 Concept design activities of a medical syringe

Table 4 Factors and weight of Customer Demands Identified

Table 5 Probability of defect occurrence in each design activity

Table 6 CPT of Customer demands identified identification

Highlights

► We proposed defect management frame.

►We constructed defect assessment mode.

► We provided defect identification method.