KCE REPORT 186B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

DÉTERMINATION DU TICKET MODÉRATEUR EN FONCTION DE LA VALEUR SOCIÉTALE DE LA PRESTATION OU DU PRODUIT





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KCE REPORT 186B
HEALTH SERVICES RESEARCH

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PRÉFACE

Comme déjà annoncé dans notre récente étude sur la simplification des tickets modérateurs, nous nous penchons dans ce rapport sur une autre implication importante de la quotepart du patient dans l'assurance maladie. Celle-ci ne sert pas uniquement à limiter la surconsommation ou le gaspillage, mais peut également avoir un effet d'orientation des choix des dispensateurs de soins et des patients. Notre système belge de remboursement joue d'ailleurs ce rôle depuis longtemps et de nombreuses façons. Ainsi, les médicaments d'importance vitale sont mieux remboursés que les médicaments de confort ; la continuité des soins est encouragée par une réduction des tickets modérateurs dans le cadre du dossier médical global et des trajets de soins.

Dans cette étude, nous approfondissons le lien entre les tickets modérateurs et la valeur sociétale des soins. Qu'en est-il à l'étranger ? Quels modèles obtiennent les meilleurs résultats ? Ce qui amène inévitablement la question suivante : qu'entend-on par « meilleurs résultats » ? Les nombreux choix qui sont souvent implicites sont ici exposés et soupesés. Des simulations concrètes montrent comment une orientation du patient dans une direction voulue, basée sur ces valeurs explicites, pourrait être traduite dans la pratique.

Nous espérons ainsi offrir un cadre de réflexion utile aux gestionnaires de notre système de santé. Par ailleurs, il n'est pas ici question de mot de la fin, il y aura encore un volet qui viendra s'ajouter à la présente étude. Il mettra l'accent sur les effets redistributifs de l'assurance maladie. Ceci est et reste un sujet complexe, qui mérite amplement qu'on y consacre une réflexion approfondie. Cela concerne somme toute un des aspects centraux de notre État-providence.

Jean-Pierre CLOSON
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RÉSUMÉ

CONTEXTE

Comme c'est le cas dans la plupart des pays, les patients payent dans le système d'assurance maladie belge une quotepart sur les coûts des soins de santé : ce sont les « tickets modérateurs ».

Quels principes doivent orienter la définition des tickets modérateurs ? Par exemple en Belgique, la catégorie de remboursement des médicaments dépend de la sévérité de la pathologie. La valeur thérapeutique ajoutée intervient uniquement dans la décision de rembourser ou non le médicament, pas dans la définition concernant le niveau de remboursement.

BUT DE L'ÉTUDE

Le but de cette étude, demandée par l'INAMI, est d'explorer des principes alternatifs de détermination des catégories de remboursement des médicaments. L'étude approfondit l'un des principes possibles, celui selon lequel le niveau du ticket modérateur est défini en fonction de la valeur sociétale du médicament. Dans la littérature anglophone, ce principe est désigné par le terme « *value-based insurance* (VBI)». L'application de la VBI ne se limite pas aux médicaments, mais peut être élargie à des prestations médicales telles que des consultations ou des actes techniques. C'est pourquoi la portée de cette étude ne se restreint pas aux médicaments.

L'étude examine les questions de recherche suivantes :

- Que signifie le principe de la « *value-based insurance* » et peut-on l'appliquer pour déterminer les tickets modérateurs ?
- De quelle manière peut-on améliorer le système actuel de tickets modérateurs ? Peut-on établir une structure de tickets modérateurs alternative basée sur le principe de la VBI ?

MÉTHODES

- Revue de la littérature portant sur la *value-based insurance* ;
- Estimation de l'impact financier d'une application possible de la VBI au remboursement des antidépresseurs, à l'aide de microsimulations.

RÉSULTATS

Principe et buts de la value-based insurance

Le principe fondamental de la *value-based insurance* est le suivant : le niveau du ticket modérateur est inversement proportionnel à la valeur sociétale d'un produit (médicament ou matériel médical) ou d'une prestation. Dans un système d'assurance social tel que le système belge, la VBI vise donc à garantir :

- l'accessibilité financière à des produits et des prestations dont la valeur est élevée ;
- un usage efficient des ressources publiques destinées aux soins de santé.

Que signifie « valeur » dans la VBI ?

Le concept de valeur dans la VBI s'entend, dans un système d'assurance sociale comme le nôtre, au sens large. Outre l'efficience (comme le rapport coût-efficacité), d'autres critères peuvent intervenir, comme la gravité de la pathologie, la prévalence, la disponibilité de traitements alternatifs et l'équité. Dans un marché d'assurance privée, comme aux États-Unis, la définition de la valeur est le plus souvent restreinte à l'efficience.

Value-based insurance et value-based pricing

La valeur peut également intervenir dans la fixation du prix, par exemple pour les médicaments. La signification du concept de valeur pour la VBI diffère cependant de celle pour le « *value-based pricing* (VBP) ». Le rapport coût-efficacité ne fait pas partie de la valeur pour le VBP, il est plutôt un instrument de négociation entre les autorités et les producteurs. Le principal objectif du VBP est la détermination d'un prix acceptable pour la société lorsque le mécanisme classique du marché échoue. L'absence de VBP peut entrainer que les objectifs de la VBI ne soient pas atteints non plus.

Formes de VBI

Dans la VBI, le ticket modérateur peut varier en fonction du produit ou de la prestation, de l'indication, de la nécessité médicale, de la nécessité thérapeutique, ou encore en fonction de la participation à un programme d'accompagnement de la prise en charge de la pathologie (*disease management programme*, DMP).

Dans le concept de **nécessité thérapeutique**, on tient compte de la sévérité de la pathologie *après le traitement standard actuel*, alors que dans le cas de la **nécessité médicale**, seule la gravité de la pathologie est prise en considération.

Différents designs peuvent coexister au sein d'un même système de soins de santé. De manière générale, la VBI avec participation à un DMP est l'approche la plus complète.

Quel que soit le design, le ticket modérateur forfaitaire est à préférer à un ticket modérateur qui est un pourcentage de la base de remboursement. Ce montant peut être fixé indépendamment du prix d'un produit ou d'une prestation. Les tickets modérateurs exprimés en pourcents ont l'inconvénient suivant : ils amènent à des montants différents pour des produits ou prestations ayant la même valeur mais des prix différents.

Mise en œuvre de la VBI

Les facteurs critiques de succès pour la mise en œuvre de la VBI sont notamment les suivants :

- disponibilité de preuves suffisantes de la valeur d'un produit ou d'une prestation ;
- bon enregistrement des données ;
- bonne communication du comment et du pourquoi des tickets modérateurs ;
- large intégration de la VBI dans le système de soins de santé.

Impact de la VBI

Actuellement, il n'y a pas encore de preuve que la VBI réduirait les dépenses de soins de santé à long terme. De même, l'impact sur la santé n'est pas démontré. La VBI améliorerait l'accès aux soins de grande valeur. Nombre d'expériences réalisées aux États-Unis pour des assurances conclues par l'employeur ont montré que la VBI, en combinaison avec un DMP, donnait les meilleurs résultats pour l'adhésion à la thérapie.

La value-based insurance en Belgique

Structure des tickets modérateurs différenciée

La structure actuelle des tickets modérateurs en Belgique est caractérisée par une différenciation importante. Exemples : les catégories de remboursement pour les médicaments, la réduction des tickets modérateurs pour les patients en possession d'un dossier médical global, le remboursement complet des tickets modérateurs pour les consultations du médecin généraliste et du spécialiste dans le trajet de soins (une forme de DMP) du diabète de type 2 et de l'insuffisance rénale chronique.

L'impact financier de la VBI pour les antidépresseurs : une illustration

Cette différenciation n'est cependant pas toujours conforme aux principes de la VBI, comme par exemple pour les catégories de remboursement des médicaments.

Comme illustration d'une application possible de la VBI pour les antidépresseurs, deux scénarios possibles ont été développées à l'aide de microsimulations.

Les deux scénarios sont construits de manières à ce qu'une durée de traitement de six mois ou plus (conformément aux recommandations de pratique clinique) soit neutre d'un point de vue budgétaire pour le patient. Les patients ayant suivi un traitement de plus courte durée sont financièrement pénalisés. L'INAMI fait des économies dans les deux scénarios, puisqu'une bonne partie des traitements actuels se limitent à la délivrance d'un seul conditionnement, le plus souvent valable pour un traitement d'un mois. Avant que la VBI ne puisse être appliquée sous cette forme, il faudra résoudre un certain nombre de problèmes pratiques de mise en œuvre.

CONCLUSION

La VBI a le potentiel d'améliorer la qualité et l'efficacité des soins de santé en stimulant l'utilisation des produits et prestations les plus valables et en décourageant l'utilisation de produit est de prestations de valeur inférieure. Outre les effets recherchés sur le comportement, la VBI implique également que les moyens publics soient utilisés de manière plus efficace. Des critères explicites sont nécessaires pour déterminer la valeur. Ces critères doivent être appliqués de manière consistante dans l'ensemble du système de soins de santé.

La VBI est donc un instrument visant à orienter la demande vers une utilisation plus efficiente des soins de santé. Un débat public doit avoir lieu concernant le degré de responsabilisation financière du patient pour l'utilisation qu'il fait des soins de santé de grande valeur.

La place de la VBI parmi d'autres incitants financiers pour des soins de santé de qualité, comme les mécanismes jouant sur l'offre (par exemple, les systèmes de paiement à la qualité), doit être déterminée. Parmi les incitants non financiers à une utilisation adéquate des soins de santé, on compte notamment le développement du disease management et du case management, les mécanismes de feedback auprès des prestataires de soins, le développement de recommandations de bonne pratique et l'information aux patients.

Simultanément, le développement d'une politique des prix dynamique est nécessaire pour préserver la viabilité financière et l'acceptabilité sociale de notre assurance maladie, qui est après tout essentiellement financée par des moyens publics.

RECOMMANDATIONS[a]

A l'attention de la Ministre et des commissions compétentes à l'INAMI

Si la mise en oeuvre de la "*value-based insurance* (VBI)" est envisagée, les recommandations suivantes peuvent être formulées :

- **Le ticket modérateur devrait être défini en fonction de la valeur sociétale de l'utilisation d'une prestation ou d'un produit. Pour l'application pratique, les catégories peuvent être basées sur des critères explicites de valeur, comme la nécessité thérapeutique et le rapport coût/efficacité incrémental.**
- **Un ticket modérateur exprimé en *pourcentage* de la base de remboursement (*coinsurance*) n'est pas compatible avec la VBI et devrait être changé par un *montant forfaitaire*.**
- **Il est souhaitable de commencer par appliquer la VBI à des produits et prestations dont les coûts et les volumes sont élevés et à travers lesquels une utilisation plus rationnelle devrait mener à une plus-value substantielle.**
- **Pour atteindre un résultat optimal, il conviendrait de coupler la VBI avec un programme de disease management (DMP) ou, par extension, de case management.**
- **La mesure dans laquelle une VBI avec participation à un DMP atteint ses objectifs devrait être évaluée. Les paramètres de résultats peuvent être : l'impact sur des dépenses spécifiques à la pathologie, l'efficacité clinique (comorbidité, complications, mortalité), la répartition (des dépenses) des soins de santé entre les groupes de population et le rapport coût-efficacité (coût par nombre d'années de vie (en bonne santé) gagnées).**
- **Dans les cas où il n'y a pas de DMP, la VBI fondée sur la nécessité thérapeutique est préférable à la VBI fondée sur la nécessité médicale. La première tient compte de la sévérité de la pathologie sous traitement standard courant, alors que la seconde prend uniquement en compte la sévérité de la pathologie sans traitement.**
- **Pour arriver à une utilisation aussi judicieuse que possible des soins de santé, la VBI devrait, en tant que mécanisme qui oriente la demande, être combinée avec des mécanismes qui agissent sur l'offre.**

[a] Le KCE reste seul responsable des recommandations adressées aux autorités publiques.

TABLE OF CONTENTS

LIST OF FIGURES **5**
LIST OF TABLES **5**
LIST OF ABBREVIATIONS **7**

■ **SYNTHÈSE** **9**
1. CONTEXTE **9**
2. DÉFINITION ET OBJECTIFS DE LA VALUE-BASED INSURANCE **10**
3. FORMES DE VALUE-BASED INSURANCE **11**
4. IMPACT DE LA VALUE-BASED INSURANCE **12**
5. PROBLÉMATIQUES DE LA VALUE-BASED INSURANCE **13**
5.1. CONDITIONS ET OBSTACLES À L'IMPLÉMENTATION D'UNE VBI 13
5.2. « VALUE-BASED INSURANCE » VERSUS « VALUE-BASED PRICING » 14
5.3. L'OPINION PUBLIQUE EST-ELLE FAVORABLE À UNE VBI ? 15
5.4. VALUE-BASED INSURANCE ET TICKET MODÉRATEUR SOUS LA FORME D'UN MONTANT FIXE OU D'UN POURCENTAGE 15
6. ILLUSTRATION D'UNE POSSIBLE APPLICATION DES PRINCIPES DE LA VALUE-BASED INSURANCE AUX MÉDICAMENTS ET IMPACT BUDGÉTAIRE **16**
7. CONCLUSION **18**

■ **SCIENTIFIC REPORT** **19**
1. INTRODUCTION **19**
1.1. GENERAL BACKGROUND 19
1.2. SCOPE AND RESEARCH QUESTIONS 20
1.3. METHODS 20
1.4. CONTENT OF THE REPORT 20
2. THE ROLE OF DEMAND-SIDE COST SHARING IN A SOCIAL INSURANCE SYSTEM **21**
2.1. DIMENSIONS OF HEALTH INSURANCE COVERAGE 21

2.1.1. Breadth of the coverage ... 21
2.1.2. Depth of the coverage ... 21
2.1.3. Height of the coverage ... 21
2.2. A BRIEF INTRODUCTION ON OPTIMAL COST SHARING ... 22
2.2.1. Cost shifting ... 22
2.2.2. Fighting moral hazard ... 22
2.2.3. Steering behaviour of imperfectly informed patients ... 23
2.3. HEALTH INSURANCE COVERAGE AND VALUE-BASED INSURANCE ... 23
2.4. DIFFERENTIATED COST SHARING IN BELGIUM ... 23
2.4.1. Disease management programme for type 2 diabetes ... 23
2.4.2. Pharmaceuticals ... 24
2.4.3. Healthcare services ... 27
3. THE CONCEPT OF VALUE-BASED INSURANCE ... 27
3.1. THE BASIC PRINCIPLE OF VALUE-BASED INSURANCE ... 27
3.2. DEFINITION OF VALUE ... 28
3.2.1. Value in value-based insurance ... 28
3.2.2. Value-based pricing ... 29
3.2.3. Value in value-based pricing ... 30
3.2.4. Issues with value-based pricing in practice ... 30
3.2.5. Value-based insurance when value-based pricing fails ... 31
4. TYPES OF VALUE-BASED INSURANCE DESIGNS ... 35
4.1. DESIGNS IN GENERAL ... 35
4.2. VALUE-BASED INSURANCE DESIGNS IN FUNCTION OF THE TYPE OF SERVICE ... 39
4.2.1. One size does not fit all ... 39
4.2.2. Belgian examples ... 41
5. ISSUES IN VALUE-BASED INSURANCE ... 43
5.1. VALUE-BASED INSURANCE AND SOCIAL PROTECTION ... 43
5.2. VALUE-BASED INSURANCE AND COINSURANCE VERSUS CO-PAYMENT ... 43

5.3. CONDITIONS FOR IMPLEMENTING VALUE-BASED INSURANCE 45
5.3.1. Evidence on the value of healthcare services 45
5.3.2. Efficient targeting 46
5.3.3. Data requirements 47
5.3.4. Auditing 47
5.3.5. Patient and physician information 47
5.3.6. Integrated approach 48
5.4. PUBLIC ACCEPTANCE AND SUPPORT FOR VALUE-BASED INSURANCE 48
6. IMPACT OF VALUE-BASED INSURANCE 49
6.1. EXPECTED BENEFITS OF VALUE-BASED INSURANCE 49
6.1.1. Impact on adherence 49
6.1.2. Impact on healthcare expenditures 50
6.1.3. Impact on access to healthcare 50
6.2. REAL-LIFE EXPERIENCES IN THE US 51
6.2.1. Value-based co-payment tiers for pharmaceuticals 51
6.2.2. Costs and outcomes of value-based insurance designs 52
6.3. EVALUATION OF VALUE-BASED INSURANCE DESIGNS IN BELGIUM 57
7. ILLUSTRATION OF A POSSIBLE APPLICATION OF VALUE-BASED INSURANCE PRINCIPLES TO ANTIDEPRESSANTS 58
7.1. OBJECTIVE AND SCOPE 58
7.2. INDICATIONS FOR ANTIDEPRESSANTS 59
7.2.1. Severe depression 59
7.2.2. Label extensions 59
7.2.3. Off-label use 59
7.3. USE OF ANTIDEPRESSANTS 60
7.3.1. Volume increase 60
7.3.2. Antidepressant treatment duration and non-persistence 60
7.4. SIMULATION OF A VALUE-BASED INSURANCE DESIGN FOR ANTIDEPRESSANTS 61
7.4.1. Microsimulation as a tool for the analysis of policy measures 61

7.4.2. Description of the data 61
7.4.3. Analysis sample 62
7.4.4. Defining a treatment episode 64
7.4.5. Social protection measures 65
7.4.6. Simulation scenarios 65
7.5. RESULTS OF THE BASELINE SITUATION 67
7.6. RESULTS OF THE SIMULATED SCENARIOS 71
7.7. DISCUSSION 76
7.7.1. Appropriateness and feasibility of a higher patient cost sharing for a first prescription 76
7.7.2. Shared responsibilities 77
8. CONCLUSION 77

■ **APPENDICES 79**

■ **REFERENCES 119**

LIST OF FIGURES

Figure 1 – Value-based principles in a drug pricing and reimbursement process 31
Figure 2 – Value-based pricing and value-based insurance 33
Figure 3 – Evolution of expenditures for antidepressants and number of patients from 2002 to 2009 (sample) 64
Figure 4 – Evolution of number of DDDs of antidepressants delivered from 2002 to 2009 (sample) 64
Figure 5 – Results of the simulation for both scenarios, by health status and socioeconomic group 73
Figure 6 – Results of the simulation for both scenarios, by age and gender 75

LIST OF TABLES

Table 1 – Drug reimbursement categories in Belgium, situation since 1 January 2012 25
Table 2 – Belgian cost sharing for statins (40 mg), patient without preferential reimbursement status 26
Table 3 – Types of value-based insurance designs 36
Table 4 – VBI designs by type of healthcare service 40
Table 5 – University of Michigan's value-based patient share tiers 52
Table 6 – Summary of the empirical evidence related to VBI 53
Table 7 – Total antidepressants delivery between 2002 and 2009 (sample) 63
Table 8 – Simulation scenarios for value-based insurance by treatment duration for antidepressants 66
Table 9 – Budget neutrality of simulation scenarios for treatment episodes of 6 months and ⩾5 packages delivered 67
Table 10 – Descriptive statistics for the treatment episodes at baseline 68
Table 11 – Category of prescriber at the start of the first treatment episode for all patients 68
Table 12 – Descriptive statistics for patient cost sharing at baseline for several population subgroups 69
Table 13 – Proportion of single package treatment episodes in each subgroup 70
Table 14 – Results of the simulation of scenario 1 for all patients 72
Table 15 – Results of the simulation of scenario 2 for all patients 72
Table 16 – Antidepressants delivery 2002 (EPS) 79
Table 17 – Antidepressants delivery 2003 (EPS) 80
Table 18 – Antidepressants delivery 2004 (EPS) 81

Table 19 – Antidepressants delivery 2005 (EPS) 82
Table 20 – Antidepressants delivery 2006 (EPS) 83
Table 21 – Antidepressants delivery 2007 (EPS) 84
Table 22 – Antidepressants delivery 2008 (EPS) 85
Table 23 – Antidepressants delivery 2009 (EPS) 86
Table 24 – Antidepressants delivery 2002-2009 (EPS) 87
Table 25 – Definition of variables used in the analysis 89
Table 26 – Simulation results of scenario 1 for different subgroups 111
Table 27 – Simulation results of scenario 2 for different subgroups 115

LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ACE	Angiotensin converting enzyme
ADHD	Attention deficit hyperactivity disorder
a.o.	amongst others
ASMR	Amélioration du service médical rendu
ATC3	Anatomical therapeutic chemical code *Level 3*
BMI	Body mass index
CNK	Code National – Nationale Kode
COPD	Chronic obstructive pulmonary disease
CTG – CRM	Commissie tegemoetkoming geneesmiddelen – Commission de remboursement des medicaments (Drug Reimbursement Committee)
DDD	Defined daily dose
DMP	Disease management programme
ED	Emergency department
EMA	European Medicines Agency
EPS_{R6}	Echantillon permanent – Permanente steekproef *Release 6*
FDA	Food and Drug Administration
FPS	Federal Public Service
GDP	Gross domestic product
GMD – DMG	Globaal medisch dossier – Dossier médical global
GP	General practitioner
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
HTA	Health technology Assessment
IBS	Irritable bowel syndrome
ICER	Incremental cost-effectiveness ratio
IMA – AIM	Intermutualistisch Agentschap – Agence Intermutualiste

LDL	Low-density lipoprotein
LYG	Life years gained
MAB	Maximum billing
MAOI	Monoamine oxidase inhibitor
NICE	National Institute for Health and Clinical Excellence
NSCLC	Non-small cell lung cancer
OCMW - CPAS	Openbaar Centrum voor Maatschappelijk Welzijn – Centre Public d'Action Sociale
OOP	Out-of-pocket
Pctl	Percentile
PR	Preferential reimbursement
Std Dev	Standard deviation
Q1 – Q3	First quartile – third quartile
QALY	Quality-adjusted life year
RB	Reimbursement basis
RCT	Randomized controlled trial
R&D	Research and Development
RIZIV – INAMI	Rijksinstituut voor ziekte- en invaliditeitsverzekering – Institut national d'assurance Maladie-Invalidité
SHI	Social health insurance
SMR	Service médical rendu
SNRI	Selective serotonin and noradrenalin reuptake inhibitor
SSRI	Selective serotonin reuptake inhibitor
TCA	Tricyclic antidepressants
USA	United States of America
VBI	Value-based insurance
VBP	Value-based pricing
WIV – ISP	Wetenschappelijk Instituut Volksgezondheid – Institut Scientifique de Santé Publique

SYNTHÈSE

1. CONTEXTE

L'une des principales caractéristiques de l'assurance maladie belge est le très large éventail de produits (médicaments et dispositifs médicaux) et de prestations qu'elle couvre pour l'ensemble de la population. Comme dans la plupart des autres pays, les patients belges assument eux-mêmes une partie des coûts de leurs soins de santé ; cette quotepart personnelle, qui peut se définir comme l'ensemble des montants non remboursés par l'assurance maladie qui leur sont réclamés au moment où ils ont recours aux structures de soins, est appelée ticket modérateur. La question de savoir comment le niveau de ce ticket modérateur doit être déterminé et selon quels principes il doit être adapté en fonction du produit ou de la prestation concernée revêt dans ce contexte une importance fondamentale. Une manière de réaliser cette différenciation serait par exemple d'appliquer des tickets modérateurs relativement faibles aux produits ou prestations de première nécessité, tandis que ceux pour lesquels il existe des alternatives plus efficientes, qui appellent un complément peu efficient ou qui ne présentent qu'une faible valeur sociétale feraient l'objet d'une contribution personnelle plus élevée. Dans la présente étude, nous nous sommes attachés à examiner le principe consistant à fixer le ticket modérateur en fonction de la valeur sociétale du produit ou de la prestation, un modèle désigné dans la littérature anglo-saxonne par le terme de « *value-based insurance* » (VBI).

Cette *value-based insurance* s'applique du reste déjà à un certain nombre de services de santé dans notre pays : ainsi, le ticket modérateur des médicaments destinés au traitement de pathologies graves est plus faible que celui des traitements utilisés dans des affections plus bénignes, les titulaires d'un Dossier Médical Global (DMG) paient une quotepart personnelle moins élevée chez leur médecin de famille et les patients qui s'engagent dans un trajet de soins déboursent moins pour les services proposés dans le cadre de ce dernier. Ces trois exemples reposent tous sur des critères de différenciation différents ; les effets concrets de la VBI, parfois involontaires voire indésirables, dépendent du paramètre utilisé.

L'Institut national d'assurance maladie-invalidité (INAMI) a demandé au KCE d'explorer les alternatives possibles au système des tickets modérateurs actuellement en vigueur en Belgique pour les médicaments, qui se base principalement sur la nécessité médicale (gravité de la pathologie en l'absence de traitement) pour fixer la catégorie de remboursement d'un produit donné. En théorie, il n'y aurait toutefois aucune raison de limiter l'application de la VBI aux médicaments – elle pourrait également être élargie, par exemple, aux consultations médicales – et le champ de cette étude dépasse donc de loin celui des produits pharmaceutiques.

2. DÉFINITION ET OBJECTIFS DE LA VALUE-BASED INSURANCE

Le principe de base de la *value-based insurance* est d'appliquer un ticket modérateur inversement proportionnel à la valeur sociétale du produit ou service considéré. En ce sens, la VBI vise :

(1) à garantir l'accessibilité financière des produits et services dont la valeur est élevée et, ce faisant, à éviter la sous-consommation des soins recommandés de par leur qualité ;

(2) à garantir l'usage efficient des moyens publics dévolus aux soins de santé. Augmenter le ticket modérateur des produits et services à faible valeur sociétale permet en effet de réserver davantage de moyens publics au financement des produits et services à haute valeur sociétale.

Dans le contexte de la VBI, la notion de « valeur (sociétale) » revêt une signification relativement large : elle est déterminée par la nécessité médicale, thérapeutique et sociale de traiter l'indication concernée, mais aussi par la valeur thérapeutique et le rapport coût-efficacité du produit. En soi, le prix n'affecte pas la valeur intrinsèque du service, mais il a évidemment un impact sur son rapport coût-efficacité relatif. Dans un contexte où la collectivité souhaite une utilisation la plus efficiente possible des moyens disponibles, il contribue donc indirectement à déterminer sa valeur sociétale.

Le recours aux principes de la VBI pour influencer la consommation des soins et/ou orienter les budgets publics vers des services spécifiques doit être murement réfléchi et comparé à d'autres mesures poursuivant la même finalité. En lieu et place ou en complément de mesures affectant directement le patient sur le plan financier, les décideurs pourraient également envisager des stimulants ciblant les prestataires et/ou les producteurs de produits de santé. Soulignons à cet égard que, même si le champ de la présente étude est limité à l'examen des tickets modérateurs, il ne faut pas en conclure que ses auteurs jugent les autres mesures moins importantes.

3. FORMES DE VALUE-BASED INSURANCE

La littérature décrit différentes formes de VBI, où l'intervention personnelle est définie en fonction du produit ou de la prestation, de l'indication, de la nécessité médicale, de la nécessité thérapeutique ou encore de la participation à un *disease management programme* (DMP). Plusieurs formes peuvent coexister au sein d'un même système de santé.

La valeur d'un produit ou d'une prestation est liée à l'indication mais aussi, in fine, au patient qui en est bénéficiaire. Elle peut donc varier en fonction de la pathologie mais aussi, à l'intérieur d'une même indication, suivant les (sous-groupes de) patients.

La VBI fondée sur le produit ou la prestation prévoit un ticket modérateur plus faible pour les produits et prestations dont la valeur sociétale est élevée, et ce pour tous les patients, quelle que soit l'indication.

La VBI fondée sur l'indication est un système dans le cadre duquel certains groupes de patients clairement définis paient un ticket modérateur plus faible (les personnes présentant des antécédents d'infarctus du myocarde paieront par exemple moins pour leur traitement hypocholestérolémiant que celles qui prennent ces produits en prévention primaire).

On peut distinguer deux formes de VBI fondée sur l'indication :

La VBI fondée sur la nécessité médicale prévoit des tickets modérateurs plus faibles pour les produits ou prestations visant des problèmes de santé sévères en l'absence de traitement (p.ex. l'insuffisance cardiaque chronique).

La VBI fondée sur la nécessité thérapeutique est un système dans lequel le ticket modérateur est plus faible pour les traitements qui présentent la valeur ajoutée la plus élevée en comparaison avec les traitements existants, lorsqu'ils ciblent des pathologies qui restent sévères en dépit du traitement standard actuel.

La VBI fondée sur la participation prévoit des tickets modérateurs plus faibles pour les patients qui participent activement à un *disease management programme* (DMP) ou à un autre module associé à des incitants comparables. Le degré de réduction du ticket modérateur pour les produits ou prestations du DMP dépend de leur valeur relative, l'idée fondamentale étant néanmoins que celle-ci est automatiquement plus élevée lorsqu'ils s'inscrivent dans le cadre d'un tel programme.

Parmi les exemples belges de VBI fondée sur l'indication, citons les mécanismes de contrôle a priori (médicaments du Chapitre IV) et a posteriori (médicaments du Chapitre II) qui s'appliquent à certains médicaments (p.ex. les statines). Suivant les conditions à remplir pour accéder au remboursement, il peut s'agir soit d'une VBI fondée sur la nécessité médicale, soit d'une VBI fondée sur la nécessité thérapeutique : si, par exemple, l'échec du traitement standard est l'une des conditions pour bénéficier d'un ticket modérateur réduit, il s'agit d'un système de VBI fondée sur la nécessité thérapeutique. Les catégories de remboursement standard qui s'appliquent actuellement aux médicaments sont par contre un exemple de VBI fondée sur la nécessité médicale, puisque ces catégories ont été définies en fonction de la gravité de la maladie. Ce système peut même être considéré comme une VBI fondée sur le produit, puisque les médicaments sont utilisés dans diverses indications sans nécessiter de contrôle a priori ou a posteriori (p.ex. dans le cas des antidépresseurs). L'attribution d'une classe de remboursement à un médicament donné relève du reste plutôt d'une procédure automatique que de considérations spécifiques dans le cadre d'un processus global ; tous les analogues de l'insuline sont par exemple intégralement remboursés, sans distinction. La nécessité thérapeutique actuelle et l'importance relative des bénéfices additionnels ne sont absolument pas prises en compte lors de l'attribution d'une classe de remboursement à un médicament, l'un des effets pervers de ce système étant qu'il est parfaitement possible qu'un nouveau produit présentant une plus-value limitée par rapport au traitement standard mais qui concerne une pathologie grave soit intégralement remboursé, tandis qu'un autre induira un surcoût pour le patient alors qu'il apporte une plus-value importante

dans une pathologie certes moins sévère, mais mal contrôlée par la thérapie standard. Une telle situation serait évidemment en contradiction complète avec les objectifs fondamentaux de la VBI, puisqu'elle reviendrait à (1) consacrer plus de moyens publics à un produit dont la valeur sociétale est faible (plus-value marginale) qu'à un médicament à valeur sociétale élevée (efficacité sensiblement supérieure) et (2) à imposer aux patients le paiement d'une quotepart plus élevée pour un médicament à haute valeur sociétale que pour un produit de moindre valeur.

4. IMPACT DE LA VALUE-BASED INSURANCE

La plus grande part de l'expérience concrète en matière de VBI nous vient des États-Unis. D'après la littérature empirique, il semble que la combinaison VBI + *disease management programme* (DMP) soit plus efficace que le recours isolé à l'une ou l'autre de ces options lorsqu'il s'agit d'encourager l'adhérence au traitement médicamenteux et l'application des recommandations cliniques.

En principe, la VBI fondée sur la participation à un DMP représente l'approche la plus complète. Elle diffère des autres formes de VBI en ce sens que le droit au ticket modérateur réduit est conditionné par une décision discrétionnaire de participer ou non au DMP. La réduction du ticket modérateur peut, du reste, être différente pour les divers produits et prestations repris dans le DMP, leurs valeurs relatives n'étant pas nécessairement identiques. Idéalement (mais ce n'est pas indispensable), des recommandations de bonne pratique basées sur des données probantes devraient tenir compte de l'ensemble des éléments qui déterminent la valeur des services de santé, faute de quoi le niveau du ticket modérateur, basé sur cette notion de valeur, pourrait être en contradiction avec les recommandations de ces directives (en d'autres termes : un traitement recommandé pourrait être associé à un ticket modérateur plus élevé).

En Belgique, les personnes qui entrent dans un trajet de soins insuffisance rénale chronique ou diabète de type 2 (une forme de DMP) sont entièrement dispensées du paiement du ticket modérateur pour certains produits et prestations spécifiques ; dans notre pays, les DMP ne concernent jusqu'ici que ces deux catégories de patients. L'Institut scientifique belge de Santé publique (ISP) s'attache actuellement à récolter une série de données relatives aux patients diabétiques participants (BMI, tension, HbA1c et cholestérol LDL), mais les résultats ne sont malheureusement pas encore disponibles. Si l'on veut pouvoir mesurer l'impact des trajets de soins sur une série de critères d'évaluation cliniquement pertinents (p.ex. la morbi-mortalité cardiovasculaire), il est indispensable de pouvoir s'appuyer sur une période d'observation suffisamment longue et sur une étude méticuleusement conçue incluant un

groupe de contrôle. Ceci n'a malheureusement pas été prévu pour les trajets de soins. En corolaire de la question de l'efficacité de la VBI, il faudrait également évaluer le rapport coût-efficacité. A court terme, on sait que la mise en place de ce type de système accroit les coûts à charge du bailleur de fonds public, puisque le remboursement des consultations augmente et qu'il faut également tenir compte du coût du matériel d'autocontrôle et des forfaits octroyés au généraliste coordinateur et au diabétologue. A plus long terme, le coût total net du programme dépendra du bénéfice qui en découlera pour la santé des patients et de l'éventuelle réduction des évènements indésirables tels que les hospitalisations. La conception des trajets de soins n'a toutefois pas prévu la présence d'un groupe contrôle en sus du groupe bénéficiant de l'intervention, ce qui complique l'évaluation de leur rapport coût-efficacité.

Il n'est par ailleurs pas encore établi que la VBI améliore réellement les résultats en termes de santé et les études empiriques n'ont jusqu'ici pas pu démontrer clairement sa capacité à réduire les dépenses totales de soins de santé. L'impact de la VBI sur ces dépenses sera déterminé d'une part par le risque clinique sous-jacent de la population traitée et la capacité des produits et prestations à valeur élevée à le réduire, d'autre part de l'importance relative du ticket modérateur pour l'adhérence au traitement et de la réduction des coûts qui découle de celle-ci. À court terme, les dépenses totales pourraient augmenter suite à la consommation accrue de produits et prestations à haute valeur sociétale associés à un faible ticket modérateur. Si l'impact de la VBI sur le coût pour les bailleurs de fonds, les patients et la collectivité doit rester neutre, il sera nécessaire d'augmenter le ticket modérateur pour les services de faible valeur afin de compenser la baisse au niveau des services à haute valeur sociétale.

Si la définition utilisée pour la « valeur » est suffisamment large, la VBI devrait avoir un effet positif en termes d'équité : elle permet en effet de réduire les obstacles financiers qui entravent l'accès à des soins de santé à haute valeur ajoutée, ce qui devrait également limiter les inégalités de santé dues aux écarts de revenus.

5. PROBLÉMATIQUES DE LA VALUE-BASED INSURANCE

5.1. Conditions et obstacles à l'implémentation d'une VBI

Les conditions à remplir pour l'implémentation d'une VBI sont :

- La disponibilité de preuves de la valeur d'un service de santé donné (nécessité médicale, nécessité thérapeutique, bénéfice thérapeutique additionnel, rapport coût-efficacité favorable, etc.) ;
- La possibilité de distinguer de manière efficiente les patients devant s'acquitter d'un ticket modérateur plus ou moins important (p.ex. identification des patients pour qui un service donné présente une valeur faible ou élevée);
- La protection de la vie privée ;
- Une collecte et un enregistrement des données très étendus ;
- Un contrôle du bon usage du système ;
- L'information adéquate des patients et prestataires sur les différences de ticket modérateur qui peuvent exister pour des services comparables dans des indications différentes ;
- L'existence d'une information accessible au public sur les principes de la VBI ;
- L'introduction de la VBI dans l'ensemble du système de soins comme l'un des principes régissant la quotepart personnelle.

Il ne s'agit toutefois pas là de conditions s'appliquant uniquement à la VBI : lorsqu'elles ne sont pas remplies, elles deviennent de véritables obstacles.

5.2. « Value-based Insurance » versus « value-based pricing »

La fixation du prix à partir de la valeur d'un produit ou service (*value-based pricing* (VBP)) est une mesure politique avancée comme une possible solution à la hausse apparemment illimitée du coût des médicaments. Son objectif est de parvenir à des prix socialement acceptables dans des situations où les mécanismes normaux du marché ne fonctionnent pas. Le principe normatif du VBP est que le coût d'un service de santé ne peut pas dépasser sa valeur sociétale, cette dernière étant définie comme la volonté de la collectivité de payer le prix dudit service, en tenant compte des limites budgétaires et des coûts d'opportunité qui accompagnent toute décision de remboursement. La valeur d'un service peut varier d'une indication à l'autre et même entre patients (ou sous-groupes de patients) à l'intérieur d'une même indication. Dans un système de VBP, ceci justifierait de pratiquer pour un même médicament des prix différents en fonction de l'indication.

La notion de valeur diffère entre VBI et VBP

La notion de valeur peut recouvrir des définitions différentes selon qu'elle s'inscrit dans un contexte de VBI ou de VBP. Le rapport coût-efficacité, par exemple, peut être un critère valide dans le cadre de la VBI, mais pas dans celui du VBP. Dans le contexte de cette dernière, le rapport coût-efficacité incrémental (ICER) pourra servir d'instrument de négociation lors de la fixation du prix ; il sera comparé à la volonté marginale de la collectivité de mettre la main au portefeuille. Dans un contexte de VBI, la mesure dans laquelle un service donné contribue à l'usage efficient de moyens limités *peut* déterminer sa valeur, dans le cas de figure où l'utilisation efficiente des moyens de santé est considérée comme un critère de valeur à part entière.

VBP et manque de transparence dans la politique de fixation des prix

Le VBP est applicable lorsque l'effet du marché est inexistant ou imparfait et que la politique de prix des fournisseurs n'est pas transparente – un cas de figure sensiblement plus fréquent pour les produits pharmaceutiques que pour des services de santé tels que les consultations médicales. Un fonctionnement déficient du marché implique que les prix ne découlent pas de l'interaction de l'offre et de la demande ; lorsque les producteurs ne fixent pas leurs prix de façon (suffisamment) transparente, il est impossible d'évaluer dans quelle mesure ceux-ci sont globalement raisonnables ou permettent d'obtenir un retour sur investissement. Précisons néanmoins que, même dans un contexte où la structure des prix des produits et services serait parfaitement transparente, des mécanismes permettant de déterminer le caractère acceptable du retour sur investissement seraient nécessaires en l'absence de VBP.

Le VBP ne peut toutefois pas être considérée comme un mécanisme destiné à corriger les effets indésirables de la position de faiblesse du bailleur de fonds public vis-à-vis du producteur : il s'agit d'un principe normatif qui peut être soulevé au cours de la discussion, mais qui ne résout en aucun cas le problème d'un pouvoir de négociation limité. Ce dernier est d'autant plus marqué lorsque chaque pays négocie de son côté avec les fournisseurs de produits médicaux : pour le fabricant, le risque de perdre un petit marché ne pèse pas bien lourd en regard de l'avantage de maintenir des prix élevés à l'échelon international. Opinion publique oblige, il est en outre parfois très difficile aux autorités de refuser un produit susceptible de sauver des vies… mais en définitive, c'est la population qui en paiera le prix, que ce soit par le biais des impôts ou d'une restriction d'autres services et avantages sociaux. Au moment où la décision doit être prise, le public n'en perçoit toutefois pas l'impact financier direct, de telle sorte que les négociations sur les prix sont souvent très limitées : toute la problématique est ramenée à la décision de remboursement, à la fixation de la base de remboursement et à celle du ticket modérateur, ce dernier pouvant être basé sur les principes de la VBI.

Interaction entre VBI et VBP

VBP et VBI sont deux approches complémentaires dans le secteur des soins de santé, l'un n'excluant donc nullement l'autre. L'échec du VBP risque toutefois d'entrainer également celui de la VBI : la décision de rembourser un produit alors qu'il n'est pas possible de négocier un prix acceptable met à mal non seulement la force du VBP en tant qu'instrument de politique, mais aussi les principes mêmes de la VBI. Les conséquences de la pression sur les prix retombent alors soit sur le patient, soit sur le payeur public, soit sur un autre intervenant (le pharmacien ou le distributeur, par exemple), ce qui revient, sauf dans le troisième cas de figure, à bafouer l'un des objectifs fondamentaux de la VBI : soit la charge financière augmente pour le patient, soit les autorités paient un prix excessif en regard de la valeur du produit, soit les deux.

5.3. L'opinion publique est-elle favorable à une VBI ?

Des données probantes empiriques limitées laissent entendre que la VBI bénéficie du soutien de l'opinion publique : les gens sont disposés à payer davantage de leur poche pour des services dont l'efficience est moindre. Outre les preuves scientifiques, il existe toutefois aussi un certain nombre d'autres facteurs perçus comme importants pour la fixation du ticket modérateur – tels que la nécessité médicale ou thérapeutique, la gravité de la pathologie étant à cet égard une considération majeure. Une variation du niveau du ticket modérateur en fonction de la valeur du service lorsque celui-ci a été recommandé par un médecin apparait par contre comme beaucoup moins acceptable.

5.4. Value-based insurance et ticket modérateur sous la forme d'un montant fixe ou d'un pourcentage

La VBI exige des tickets modérateurs fixes, fixés indépendamment du prix du produit ou de la prestation ; ce système n'est pas compatible avec des tickets modérateurs correspondants à un pourcentage du prix du produit ou de la prestation, car la quotepart personnelle risque alors d'être différente pour des services équivalents mais tarifés différemment. Le prix peut en effet varier en fonction d'autres paramètres que la valeur, par exemple des différences au niveau du coût de la recherche et du développement (R&D). La VBI n'est pas non plus compatible avec les catégories de remboursement des médicaments telles qu'elles existent actuellement en Belgique, qui sont également basées sur des pourcentages fixes. Dans ce système, un produit à haute valeur (incrémentale) peut en effet correspondre à un ticket modérateur plus élevé qu'un autre dont la valeur (incrémentale) est plus faible, pour peu que son prix de base soit plus élevé et qu'il appartienne à une catégorie de remboursement plus faible. Sous l'angle de la VBI, mieux vaut donc déterminer les catégories de remboursement en fonction de la valeur ajoutée des médicaments, le ticket modérateur correspondant à un montant fixe.

Les réserves vis-à-vis de catégories de remboursement prédéfinies basées sur des tickets modérateurs calculés en pourcentage sont les mêmes, que le prix du médicament se base ou non sur sa valeur. Elles s'appliquent en outre également, fût-ce d'une manière différente, à d'autres services de santé tels que les consultations médicales. Les honoraires de consultation en médecine spécialisée, qui peuvent varier de façon considérable selon le secteur, en sont le meilleur exemple dans notre pays : bien que ce fossé entre spécialités soit sans lien avec la valeur du service, le calcul du ticket modérateur sous forme de pourcentage a pour conséquence que le patient devra s'acquitter pour chacune d'une quotepart différente. Une telle situation est évidemment incompatible avec les principes de la VBI, même s'il importe de préciser qu'un plafonnement du ticket modérateur (tel qu'il existe pour les médicaments) contribue à réduire cet effet. Remplacer ces pourcentages par des tickets modérateurs fixes serait pourtant une alternative parfaitement possible.

6. ILLUSTRATION D'UNE POSSIBLE APPLICATION DES PRINCIPES DE LA VALUE-BASED INSURANCE AUX MÉDICAMENTS ET IMPACT BUDGÉTAIRE

A titre d'illustration, nous avons exploré pour une classe de médicaments soumis à prescription (les antidépresseurs, en l'occurrence) une alternative potentielle au système actuel de VBI fondée sur la nécessité médicale. Notre exemple se borne à examiner une seule alternative (un système de VBI fondée sur l'indication), mais en principe, d'autres modèles sont également envisageables (p.ex. VBI avec participation à un *disease management programme* (DMP), dans l'hypothèse où un tel programme serait mis sur pied). L'impact budgétaire de la mesure a été calculé pour le patient et pour l'INAMI. Il convient de préciser ici que le caractère limité des données administratives utilisées (p.ex. absence de données diagnostiques pour les patients ambulatoires, incertitude quant aux causes d'interruption du traitement…) nous a forcés à nous baser sur un certain nombre de suppositions ; ces aspects devraient évidemment être clarifiés avant une éventuelle mise en pratique. Nous avons notamment rendu explicites des jugements de valeur implicites, tout en nous efforçant de les replacer dans leur contexte. Nous sommes également partis du principe que les changements de ticket modérateur de notre simulation n'entraineraient pas de changements de comportement – une position qui est évidemment discutable et demanderait à être soit justifiée, soit revue dans l'hypothèse où les principes de la VBI seraient effectivement appliqués aux antidépresseurs. Des recherches et analyses plus approfondies seraient donc nécessaires avant une éventuelle application des principes de la VBI à ce domaine.

Les médicaments antidépresseurs sont indiqués dans le traitement des dépressions majeures et des troubles anxieux, paniques et obsessionnels-compulsifs. Suivant les recommandations de bonne pratique clinique, une utilisation à relativement long terme – au moins six mois après l'obtention d'une réponse satisfaisante – est nécessaire pour retirer de ces médicaments un bénéfice de santé optimal. Des données belges et étrangères révèlent toutefois que les antidépresseurs sont aussi régulièrement utilisés dans d'autres indications (parfois non reconnues) ou pour des périodes plus brèves.

À l'heure actuelle, ces traitements sont remboursés par l'assurance maladie dans le cadre d'un système de VBI fondée sur le produit, ce qui implique que le niveau du ticket modérateur est identique dans toutes les indications. Ils sont remboursés en catégorie B, ce qui correspond à une quotepart personnelle de l'ordre de 25 ou 15%, selon que le patient a ou non droit à une intervention majorée ; ce pourcentage est fixé sur la base d'une évaluation de la gravité de l'indication principale du médicament. Dans la mesure où les bases de données administratives relatives aux patients ambulatoires ne comportent pas à l'heure actuelle d'informations diagnostiques, une VBI fondée sur l'indication n'est à ce jour pas du domaine du possible. Nous avons donc utilisé la durée du traitement comme critère de substitution pour l'indication, en partant du principe qu'un traitement de six mois ou plus concerne une dépression majeure, un trouble panique, un trouble anxieux ou un trouble obsessionnel compulsif. Ce modèle de VBI pose un jugement de valeur, car les indications qui demandent un traitement plus prolongé par antidépresseurs sont considérées comme plus importantes que celles qui ne nécessitent qu'un traitement à court terme, et justifient donc des dépenses publiques plus élevées.

Nous avons simulé deux scénarios, conçus de manière à ce que le coût pour le patient d'un traitement de six mois ou davantage soit le même que dans la situation actuelle. Les analyses se basent sur l'échantillon permanent (EPS) pour la période de 2003 à 2009. Les simulations prévoient toutes deux pour la première boite un remboursement plus faible que pour les suivantes et inférieur au ticket modérateur actuel : remboursement de 0% (bénéficiaire ordinaire) – 40% (BIM) dans le premier scénario et de 25% (bénéficiaire ordinaire) – 55% (BIM) dans le second.

Dans notre simulation, contrairement à ce que l'on observe dans la situation actuelle, les patients qui ne reçoivent qu'une seule prescription paient donc davantage que ceux qui en reçoivent plusieurs. Ce cas de figure concerne environ 46% des épisodes de traitement identifiés entre 2003 et 2009 dans l'EPS ; extrapolé à l'ensemble du pays, cela correspond à quelque 1 337 000 périodes de traitement ayant fait l'objet d'une prescription unique.

La redistribution du ticket modérateur par boite en fonction des épisodes de traitement a débouché sur une économie pour l'INAMI en comparaison avec la situation actuelle, et ce pour les deux scénarios examinés. Cela s'explique par le fait qu'un grand nombre de périodes de traitement ne reposant que sur une seule boite ne seraient soit plus remboursés du tout, soit moins remboursés qu'à l'heure actuelle. Des analyses comparant différents sous-groupes de patients démontrent que le surcoût de ce système pour les patients BIM, à faibles revenus, malades chroniques ou handicapés est en moyenne plus faible que pour les autres. Une simulation révèle néanmoins que les patients qui touchent une allocation de chômage complète paient proportionnellement plus que ceux qui ne touchent pas d'allocations de chômage.

La mise en œuvre d'un modèle de VBI tel qu'il a été simulé pour les antidépresseurs risque toutefois de se heurter à une série d'obstacles. Pour déterminer le montant du ticket modérateur, le pharmacien devrait par exemple savoir si le patient a déjà fait l'objet d'une prescription d'antidépresseurs dans un passé relativement récent ; ceci implique également que la première prescription, non remboursée, soit enregistrée, ce qui ne se fait pas aujourd'hui de façon systématique pour les traitements non remboursés. Une autre possibilité serait de faire effectuer les remboursements a posteriori par les mutuelles, puisque celles-ci ont accès au nombre de prescriptions pour chaque bénéficiaire ; cela signifie toutefois que les patients devraient avancer le prix du médicament, ce qui risque de mettre à mal l'adhérence thérapeutique. Le remboursement des antidépresseurs dans d'autres indications est également problématique : si les règles ne sont pas les mêmes que pour la dépression, il sera indispensable de procéder en routine à l'enregistrement des informations diagnostiques des patients ambulatoires dans les bases de données administratives.

En dépit des réserves formulées plus haut, cette simulation a le mérite de démontrer qu'il existe plusieurs manières de rembourser les médicaments soumis à prescription. Même si l'alternative examinée ici n'est pas optimale (des analyses plus approfondies et une évaluation détaillée seront nécessaires pour décider du modèle de VBI le plus approprié), il convient de se demander dans quelle mesure le système actuel est réellement meilleur ; il est en effet du devoir des décideurs de soulever ce genre d'interrogations afin d'éviter l'écueil de la résistance au changement.

7. CONCLUSION

Dans un contexte où les ticket modérateurs sont considérés comme un mécanisme acceptable pour influencer les comportements et favoriser l'utilisation efficiente des moyens publics, la VBI est susceptible d'améliorer la qualité et l'efficacité des soins de santé en stimulant le recours aux produits et prestations à haute valeur sociétale et en décourageant l'utilisation de ceux dont la valeur est faible. Ceci nécessite toutefois des mécanismes permettant (1) de définir la valeur du produit ou de la prestation et (2) de cibler efficacement les réductions de ticket modérateur. La première de ces exigences impose de disposer de critères explicites pour déterminer la valeur des produits ou prestations et de les appliquer de façon cohérente dans l'ensemble du système de soins. La seconde demande des outils TIC adéquats et un contrôle du caractère approprié de l'information dispensée.

La VBI est donc un instrument qui permet d'orienter la demande de manière à parvenir à un usage efficient des structures de soins. Un débat sociétal est toutefois nécessaire pour déterminer dans quelle mesure le patient doit être rendu financièrement responsable de sa consommation ressources de santé de valeur.

Il convient également de définir la place de la VBI à côté d'autres incitants financiers en faveur de soins de haute qualité, et notamment des mécanismes qui agissent sur l'offre (p.ex. des systèmes qui récompensent financièrement la qualité (*pay-for-quality)* à l'intention des médecins et fabricants de produits de santé) ou des systèmes de franchise pour les patients. La coexistence de différents modèles est parfaitement envisageable. Une logique de VBI peut par exemple garantir une offre complète de services de qualité qui seraient, dans d'autres circonstances, pris en compte dans le calcul de la franchise. L'harmonisation des stimulants cliniques et financiers pour les patients et les prestataires favorisera l'utilisation de soins de haute qualité tout en décourageant celui de services dont la valeur est faible ou non prouvée.

Les stimulus non financiers visant à améliorer le bon usage des soins de santé recouvrent notamment le développement de *disease management programmes* ou de *case management*, les mécanismes de feedback pour les prestataires, le développement de recommandations de bonne pratique clinique et l'information des patients. En parallèle, il est toutefois nécessaire de développer une stricte politique de prix afin de garantir la pérennité financière et l'acceptabilité sociétale de notre système d'assurance maladie, financé principalement par des moyens publics ; les possibilités à ce niveau sont notamment des négociations de VBP à l'échelon international, le recours à des montants de référence ou encore des mécanismes de partage des risques.

SCIENTIFIC REPORT

1. INTRODUCTION

1.1. General background

The Belgian health insurance system is characterized by coverage of nearly the entire population for a wide range of services[a]. Healthcare consumption is reimbursed, though cost sharing between public authorities and patients is an inherent feature of the system. Conventional theoretical models of health insurance emphasize the trade-off between the welfare gains from financial risk reduction for the patient and the welfare loss from moral hazard due to a reduction of financial barriers. The way this trade-off is resolved, depends crucially on the weight attached to principal values of a healthcare system, such as efficiency, access to good quality care and equity. The tension between these values has always been present in the Belgian healthcare and health insurance system.

A basic question is how -i.e. based on which principles- the level of cost sharing for healthcare services should be defined. Possible principles are lower cost sharing for higher needs of patients with a disease, lower cost sharing for patients at higher risk of getting a disease, higher cost sharing for services with more efficient substitutes, higher cost sharing for services with inefficient complementary services and higher cost sharing for low-value services (these principles have been described in a previous KCE report about the simplification of the cost-sharing structure of general practitioner (GP) visits and consultations and specialist consultations[1]).

In Belgium, pharmaceutical products are classified in coinsurance categories according to the severity of the disease or condition. It is thus a disease-based system. Currently, added therapeutic value is only used to determine whether or not a product should be reimbursed. It is not used to determine the reimbursement category. Category A consists of products of vital importance for patients with a life-threatening condition. Category A drugs are fully reimbursed. Category B consists of important though not vital products, such as antibiotics. The coinsurance level depends on the status of the patient (entitled or not to preferential reimbursement) and is

[a] We use the term services to refer to services and products (drugs and medical devices) unless otherwise stated.

capped. Other categories are C, Cs, Cx and D (see Table 1 on page 25). Products in category D are, in general, not reimbursed. Within the Drug Reimbursement Committee (CTG – CRM) of the National Institute for Health and Disability Insurance (RIZIV – INAMI), discussions are taking place about the appropriateness of the current disease-based approach to define the reimbursement category of a drug. Moreover, questions are raised about how evolutions in diseases or treatments can be taken into account.

1.2. Scope and research questions

KCE was asked by RIZIV – INAMI to study alternative principles to define the reimbursement category of a drug.

This study focuses on one particular principle, called value-based insurance (VBI). In value-based insurance, the level of cost sharing varies with the societal value of the service. The scope of VBI and of this study is, however, not limited to drugs but applies to healthcare services in general.

The report addresses two research questions:

1. What is value-based insurance? How can it be used to determine the level of cost sharing?
2. How can new VBI designs be implemented or existing designs be improved in the Belgian health insurance system?

1.3. Methods

The main purpose of the study is to make methodological recommendations in case of implementation of VBI in the Belgian system. The recommendations will be based on an assessment of the available literature on VBI and an analysis of Belgian data.

The first research question will be studied by a review of the literature on VBI.

A possible implementation of VBI in the Belgian health insurance system for one particular prescription drug is explored using a microsimulation technique, applied to a dataset with demographic and socioeconomic information, and healthcare expenditures for a random sample of Belgian residents with public health insurance coverage.

More details on the methods and dataset will be provided in the following chapters.

1.4. Content of the report

The report is organized as follows.

Chapter 2 contains the basic underlying principles of demand-side cost sharing in a social health insurance system and gives some examples of the differentiated structure of cost sharing in Belgium. In Chapter 3 we describe the basic principle of VBI (3.1) and define the concept of “value” (3.2) in value-based insurance and in value-based pricing. Next, we develop a taxonomy of VBI designs (Chapter 4) and discuss some issues in VBI (Chapter 5): the relation between VBI and social protection mechanisms (5.1); the implications of coinsurance in a VBI design (5.2); conditions for implementing VBI (5.3) and public acceptance of VBI (5.4). To get an idea of the possible impact of VBI, we first describe the theoretical expected benefits (6.1), then give some real-life experiences in the United States (6.2) and conclude with some methodological issues encountered in the evaluation of VBI designs (6.3). In Chapter 7 we illustrate the potential budgetary impact, for patients and the RIZIV – INAMI, of a VBI design applied to a prescription drug. Section 8 concludes.

2. THE ROLE OF DEMAND-SIDE COST SHARING IN A SOCIAL INSURANCE SYSTEM

This chapter serves as a brief introduction on the role of demand-side cost sharing in a social health insurance system such as Belgium. It is, however, beyond the scope of this study to review the theoretical literature on the optimal design of insurance and cost sharing or the empirical support for predictions found in the theoretical literature. Instead, we summarize some standard results of the conventional theory of insurance design and indicate where value-based insurance comes into play. A next KCE report on cost sharing will elaborate on the optimal design of cost sharing and protection mechanisms. We end the chapter with a description of some examples illustrating the current differentiated structure of cost sharing in Belgium.

2.1. Dimensions of health insurance coverage

Health insurance coverage can be defined in terms of three dimensions. The first dimension is the **breadth** of the coverage referring to the proportion of the population covered. The second dimension, the **depth** of the coverage, refers to the range of services covered and is also called the benefits package. The third dimension is called the **height** of the coverage and refers to the proportion of the total cost covered by insurance. The remaining part of covered services is paid directly by patients. The next paragraphs briefly describe the three dimensions for the Belgian social health insurance system.

2.1.1. Breadth of the coverage

Belgium has a compulsory, social health insurance (SHI) system with entitlement based on enrolment in one of the sickness funds and payment of an income-dependent contribution (with exemptions for certain groups). More than 99% of the Belgian population is covered by the SHI system. The uninsured population includes persons who did not accomplish the formalities necessary to be inscribed in a sickness fund or who did not pay their contribution on time.

2.1.2. Depth of the coverage

All sickness funds have to provide an identical benefits package in Belgium. The benefits package is very broad and includes physician services, hospital care, prescription drugs, most physiotherapy, most dental care, home health care, nursing home care, psychiatric care, etc. Not included or hardly reimbursed are spectacles, contact lenses, hearing aids, occupational therapy (except in the context of rehabilitation in an institution), orthodontic care, (most) plastic surgery, non-urgent transport to the hospital, less necessary drugs (called reimbursement category D) and non-traditional therapies such as acupuncture and homeopathy. Covered services are explicitly defined in the nationally established fee schedule or so-called nomenclature, containing the fee and reimbursement level for all items that are completely or partially reimbursed by the sickness funds. The nomenclature lists more than 8 000 services. Services not covered by the fee schedule are not reimbursable. There exists a comparable list for reimbursed drugs.

2.1.3. Height of the coverage

Patient or demand-side cost sharing is the direct payment by patients of a share of the costs of healthcare at the point of use. In general, three direct forms of cost sharing can be identified: co-payments, coinsurance and deductibles. A **co-payment** is a fixed fee (flat rate) per item or service. In case of **coinsurance** the patient pays a percentage of the cost of the service. Both forms are dominant in most European healthcare systems. With a **deductible**, patients have to pay all healthcare costs up to a certain limit before coverage begins. Combinations of these three forms of cost sharing are also possible.

Two cost-sharing arrangements co-exist in the Belgian system: for some services patients pay a percentage of the price or fee (coinsurance), e.g. 25% of the drug price; for others they pay a fixed amount (co-payment), e.g. €6 for a GP consultation. We use the term “patient share” or “cost sharing” when the distinction between co-payment and coinsurance is not relevant.

In addition to co-payments, coinsurance and deductibles, some indirect forms of cost sharing exist. These include the difference between official tariffs and freely set fees by providers, called “supplements” in Belgium, “dépassements” in France and “balance billing” in the United States of America (USA), charges in excess of some amount (e.g., the cost of prescription drugs in excess of a reference price) and healthcare services not covered by the insurer.

In the current study, the scope of patient cost sharing is limited to co-payments and coinsurance.

2.2. A brief introduction on optimal cost sharing

Different kinds of arguments are given in the health economics literature to justify patient cost sharing. There is, however, still no consensus in the empirical work about the size of the theoretically expected effects.

2.2.1. Cost shifting

A first reason for having cost sharing is to raise revenue for the healthcare system in a way that the burden of the public budget is reduced. For example, in 1993 there was a shift of about 2% of the total public healthcare budget to patients through increased co-payments and coinsurance rates, due to the economic recession and the commitments accepted by the Belgian government to join the European Monetary Union.[2] Of course, (fiscal) equity considerations are of primary importance in case of cost shifting. The design of cost-sharing structures and protection mechanisms determine the distribution of the financial burden for different patient groups. Hence, confronted with the social consequences of increased cost sharing, the Belgian government decided in 1994 to introduce exemption schemes to put a ceiling on the total amount of cost sharing to be paid by the patients. These have resulted later in the maximum billing system.

2.2.2. Fighting moral hazard

In addition to cost shifting, cost sharing has also the intention to increase patients’ cost-consciousness and discourage unnecessary or too expensive care. Insurance reduces the marginal cost of healthcare to the patient (to zero in case of full insurance and neglect of time cost) and patients purchase more care than they would have purchased if they had had to pay the full price. This consumer demand response to insurance is called moral hazard. It is often argued that cost sharing restores the price signal negated by insurance, and reduces the social welfare loss caused by this excess use. An underlying assumption is that the price signal will selectively discourage the use of ineffective or unnecessary healthcare services. According to economic theory, coverage should be inversely related to the demand elasticity or price responsiveness of the covered service. However, this standard result in the optimal insurance literature is based on the assumption that the demand curve for healthcare correctly reflects the marginal benefits of a service, which requires patients to be fully informed to make good choices.[3]

In a real-world social health insurance system, multiple services are covered. These services can be complements or substitutes. Changing health insurance coverage (and hence cost sharing) for one service may affect the use of other insured services. The magnitude of this offset effect depends on the cross-price elasticity between both services. For example, increased coverage for drugs may lead to offsets in use of hospital services.

2.2.3. Steering behaviour of imperfectly informed patients

A third argument for cost sharing is to provide patients with monetary incentives to alter their behaviour towards the consumption of specific, e.g. more cost-effective, care. Belgium has a long tradition of differentiated co-payments and coinsurance rates, often in an effort to steer patients. We come back to the differentiated structure of cost sharing in Belgium in section 2.4.

For the argument of altering patient behaviour to be useful, one of the assumptions of both previous arguments should be relaxed. There it was assumed that patients have sufficient information to take rational decisions and are able to distinguish between effective and ineffective care. In general, patients do not have the information necessary to evaluate medical care and to make good choices. Various studies have shown that patients make mistakes in their demand for healthcare.[4] These consumer mistakes have, however, implications for the optimal design of health insurance and cost sharing, which depends on whether patients under- or overvalue healthcare (see McGuire (2012)[4] for an algebraic analysis). Imperfectly informed patients who are confronted with cost sharing, will not necessarily balance the cost and clinical value of services in an optimal way and their demand curves do no longer reflect the marginal benefits of services.[5] Offset effects also play an important role in steering patients.

2.3. Health insurance coverage and value-based insurance

The first decision to be taken in a social health insurance system is about what services to include in the benefits package. The broader the definition of the basic benefits package, the smaller the role for individual responsibility and the larger the scope of solidarity. The benefits package and entitlement to benefits reflect underlying societal values in a given country. Given a limited budget, choices have to be made about which health services to reimburse and, by implication, which will not be reimbursed.

Once the benefits package is defined, the second decision to be made is how much the services, included in the benefits package, should be covered. As we will see in the following chapters, value-based insurance is primarily relevant for defining the height of the coverage. Of course, when patient cost sharing is equal to zero and the healthcare service is not reimbursed, the height and depth dimension coincide.

There is some empirical evidence that (conventional) cost sharing reduces both inappropriate and appropriate healthcare utilization, because patients have insufficient information or are unable to distinguish between appropriate or necessary and inappropriate or optional care.[6] As we will show in the following chapters, value-based insurance has the potential to steer patients towards high-value healthcare and to avoid patient mistakes due to imperfect knowledge. Moreover, equity considerations can be directly incorporated in the cost-sharing structure.

2.4. Differentiated cost sharing in Belgium

Co-payments and coinsurance rates are highly differentiated in Belgium. Although official policy documents rarely mention the precise role of the differentiated cost-sharing structure, some of the measures are clearly meant to steer patients towards cheaper drugs or specific care programmes for the chronically ill. Later in the report we come back on some of the examples and discuss the current cost-sharing structure in terms of the theory of VBI.

2.4.1. Disease management programme for type 2 diabetes

Different healthcare models for the treatment and management of type 2 diabetes patients exist in Belgium. The care pathway model for type 2 diabetes patients, called “care trajectory” (zorgtraject - trajet de soins), was launched in September 2009. A care trajectory is based on the collaboration between three parties, namely the GP, a specialist (mainly endocrinologist) and the patient. It organizes and coordinates the treatment and follow-up of patients with a chronic illness (i.e. diabetic patients) and can be considered as the Belgian adaptation of the Chronic Care Model developed by Wagner, which is an evidence-based set of principles for improving chronic care.[7,8] All type 2 diabetes patients with 1

or 2 daily insulin injections or incretin mimetic drugs, or patients on maximal oral therapy with initiation of insulin treatment considered, can initiate the care trajectory. Pregnant diabetics and diabetic patients with a desire to have children, are excluded.

Already in 1987, a disease management programme (DMP) for diabetic patients was organized in Belgium, namely the diabetes convention. The diabetes convention is an agreement between hospitals ("revalidation centres") and RIZIV - INAMI. Patients with at least two insulin injections per day are entitled to an educational programme by a multidisciplinary team and receive free of charge material for home blood glucose monitoring. Partly on the basis of the recommendations of KCE report 27A, the care trajectories were initiated to create primary care diabetes teams with a reinforced role for the GP.[7] GPs have no gatekeeping role in Belgium. In the care trajectories, the GP is the coordinator of the care. He elaborates a treatment plan in close consultation with the patient, including individual quantified targets for the control of glucose, blood pressure and blood lipids. The treatment plan for the patient's self-management of diabetes is also approved by the endocrinologist. In addition to the self-management support, the use of evidence-based clinical practice guidelines by all health care workers concerned is one of the central elements of the Chronic Care Model and of the care trajectories.

The patient, who signs a four-year agreement, has a number of obligations. First, a minimum number of physician-patient contacts are required: two consultations per year with the coordinating GP and one with the diabetes specialist. Second, he has to open a global medical record (GMD - DMG) with the coordinating GP. Patients are encouraged to enter the program by financial incentives. These include total reimbursement of all consultations (at the moment of writing home visits are not included) with the coordinating GP, total reimbursement of consultation(s) with the diabetes specialist, partial reimbursement of dietician and podiatrist consultations, reimbursement of diabetes education and free access to self-management education materials such as glucose meter, glucose test strips and lancets.

Insulin is fully reimbursed in Belgium (drug category A), irrespective of participation in a DMP.

The coordinating GP and diabetes specialist receive an annual lump sum payment of €80 at the time of writing. Periodic reporting by the GP of the following parameters is required: BMI, blood pressure, hemoglobin A1c (HbA1c) and LDL (low-density lipoprotein)-cholesterol.

2.4.2. Pharmaceuticals

The underlying principle of the cost-sharing mechanism for pharmaceuticals in Belgium is that the level of cost sharing should decrease the more severe the condition. In practice, it is often -though not always- disease severity *without treatment* that determines the level of cost sharing. This corresponds to the notion of medical need. In contrast, a system based on therapeutic need considers disease severity after current standard treatment. We come back on these concepts in Chapter 4. Other criteria, such as cost-effectiveness, added therapeutic benefit or social importance are not considered for the determination of the level of cost sharing for pharmaceuticals. These criteria are, however, taken into account in the decision to reimburse a drug. The reimbursement decision thus precedes the cost-sharing decision and is based on a larger range of criteria.

Table 1 – Drug reimbursement categories in Belgium, situation since 1 January 2012[b]

Category	Therapeutic importance	Cost sharing in community pharmacies defined as a percentage of the $RB_{ex\text{-}factory*}$	Cost sharing in hospital pharmacies for ambulatory patients defined as a percentage of the RB[c]
A	Vital drugs (e.g. insulin, cancer drugs)	0%	0%
B	Therapeutically significant drugs for non-life threatening diseases (e.g. antibiotics, antiasthmatics, antihypertensives)	Patients without PR**: 44.20% if $RB_{ex\text{-}fact}$< €14.38 €2.5 + 27% if $RB_{ex\text{-}fact}$ ≥ €14.38 Capped coinsurance: - €11.30 - €14.10 for large packages	Patients without PR: 25% Capped coinsurance: - €11.30 - €14.10 for large packages***
		Patients with PR: 26.52% if $RB_{ex\text{-}fact}$< €14.38 €1.5 + 16% if $RB_{ex\text{-}fact}$ ≥ €14.38 Capped coinsurance: - €7.50 - €9.30 for large packages	Patients with PR: 15% Capped coinsurance: - €7.50 - €9.30 for large packages
C	Therapeutically less significant drugs for symptomatic treatment (e.g. antiemetics, spasmolytics)	88.39% if $RB_{ex\text{-}fact}$< €14.38 €5 + 54% if $RB_{ex\text{-}fact}$ ≥ €14.38 Capped coinsurance: Patients without PR: €14.10 Patients with PR: €9.30	50% Capped coinsurance: Patients without PR: €14.10 Patients with PR: €9.30
Cs	Drugs used in certain chronic illnesses (e.g. antihistamines and vaccines)	106.07% if $RB_{ex\text{-}fact}$< €14.38 €6 + 65% if $RB_{ex\text{-}fact}$ ≥ €14.38	60%
Cx	Contraceptives and antispasmodics	141.43% if $RB_{ex\text{-}fact}$< €14.38 €8 + 86% if $RB_{ex\text{-}fact}$ ≥ €14.38	80%

** RB = reimbursement basis (usually equals the pharmacy retail price); $RB_{ex\text{-}factory}$ = reimbursement basis ex-factory (usually equals the ex-factory price)*
*** PR = preferential reimbursement*
**** Large packages contain more than 60 units of drugs*

[b] On 1 April 2010, the reimbursement and cost-sharing levels were modified.[9] The division into categories has remained the same as before, as are the basic principles of the cost-sharing arrangements. The ceilings for the patient share are those prevailing since 1 January 2012.

[c] Hospitalized patients pay €0.62 per day, independent of their actual drug use. Also patients who do not use drugs, pay this lump sum.

In addition to the reimbursement categories in Table 1, patient cost sharing may depend on patient type and brand versus low cost drugs. For statins, for instance, patient cost sharing is higher for indications for which the effectiveness of statins is lower. In addition, the patient share also varies by brand in order to stimulate the use of the lower-priced products. An example for statins is provided in Table 2.

Table 2 – Belgian cost sharing for statins (40 mg), patient without preferential reimbursement status

	Simvastatin	Lipitor®	Pravasine®
	Generic product	Brand product, without supplement*** on top of patient share	Brand product, with supplement on top of patient share
With prior approval*	€0.00	€0.00	€3.97
Without prior approval**	€5.58	€13.70	€17.67

** Prior approval entitles patients to reimbursement in category A (100% of the reimbursement basis). The approval is subject to strict conditions related to the proof of clinical status leading to the highest potential benefit. For instance, reimbursement in category A applies to patients with proven hereditary severe hypercholesterolemia.*
*** Without prior approval, the reimbursement is lower. This usually applies to conditions for which the estimated value is lower than for cases reimbursed in category A with prior approval. In the case of statins, this applies to primary prevention of cardiovascular events in specific patient groups, secondary prevention and diabetes patients. Recommendations for use are formulated and physicians should keep patient records with information that can prove their compliance with the recommendations.*
**** The supplement is called "reference supplement" and applies to those original drugs where a low-cost alternative is available. It is equal to the difference between the price and the reimbursement base.*

2.4.3. Healthcare services

Differentiation in cost sharing in Belgium is not limited to drugs or a DMP but it is also used to steer patients towards specific services. A first example is the reduced patient share for visits to the **emergency department** (ED) if preceded by a referral from the GP. Although the concrete modalities have changed several times, the underlying idea is to reduce unnecessary reliance on hospital EDs and to redirect patients to primary care services.

Patients with a **global medical record** pay reduced coinsurance rates for consultations with the general practitioner who manages or has access to the GMD – DMG. The measure was introduced on 1 May 1999 for patients over 60 years and extended to patients over 50 years and to all ages on 1 May 2001 and 1 May 2002 respectively. On 1 June 2000 the range of application was extended to GP visits of patients over 75 years and to some chronically ill. Since 1 April 2011 a prevention module that facilitates preventive healthcare maintenance of patients aged 45-75 is added to the GMD – DMG. Based on a checklist, once a year the GP discusses with the patient which preventive health measures could be useful. The patient pays €10.14 but this amount is fully reimbursed.

A third example relates to **specialist services**. Patients have direct access to specialist care in Belgium. To stimulate patients to see their GP before consulting a specialist, a reduction in patient cost sharing for specialist care for patients who are referred by their GP was introduced in 2007. The measure, however, was limited in scope. The reduction only applies to the first specialist consultation per calendar year and per specialism. The reduction amounts to €5 for the general population and €2 for patients eligible for preferential reimbursement.

3. THE CONCEPT OF VALUE-BASED INSURANCE

3.1. The basic principle of value-based insurance

In value-based insurance (VBI) the level of cost sharing for services is a function of the value of the benefits of these services: the higher the value, the lower the level of cost sharing. By reducing or eliminating cost sharing for high-value healthcare services, and increasing cost sharing for low-value healthcare services, the demand-side effect -i.e. reduced utilization- of cost sharing is expected to be most prominent for low-value services.[10] At the same time, VBI targets public health expenditures to health services that are considered of highest value. Public expenditure for a service can be considered as the complement of the patient's share in the cost of that service: the higher the patient's share, the lower the public expenditure and vice versa. When VBI is used to ensure that public resources are well spent, the basic principle is that the public preparedness to pay should be higher for high-value services than for low-value services. Therefore, the level of reimbursement has to be relatively higher for high-value services than for low-value services and as a consequence the patient share should be lower. The same principle may thus serve two objectives:

1. to ensure financial access to high-value healthcare services, and
2. to ensure that public resources are well spent (targeting public expenditures towards healthcare that offers "value for public money" – efficient resource allocation).

Most literature on VBI originates from the USA, where the insurance system is characterized by a large private sector, combined with managed care. The objective of VBI in this context might be slightly different from the objective in a social security context. For-profit private insurers aim to spend their income from insurance premiums efficiently, i.e. maximize income and minimize costs. They have an interest in patients' adherence to high-value treatments, because non-adherence may induce more healthcare costs in the long run, leading to lower profits, higher premiums and lower attractiveness of their health insurance plan. Hence, in a context with a large for-profit private health insurance sector, the reason for

implementing VBI is to steer consumption behaviour in order to reduce healthcare expenditures. The second objective should be rephrased as "to ensure that private resources are well spent (targeting healthcare expenditures towards healthcare with the highest cost-benefit ratio, where cost-benefit is defined in monetary terms)".

In social security-types of healthcare systems as in Belgium and France, VBI is frequently used to steer patients toward more efficient patterns of healthcare use, e.g. by reducing the patient share for specialist visits when these are performed in the context of a disease management programme.[11] VBI is in this context not used to reduce expenditures per se, although it might be part of it, but rather to target public expenditures towards services that offer the highest societal value. The efficiency concept is different/broader than in the case of private insurance systems, where efficiency has a stronger financial connotation. In a social security-type system, efficiency is determined by value defined in a broad way (see paragraph 3.2).

The basic principle of value-based insurance is that cost sharing for high-value services should be lower than cost sharing for low-value services.

In a social security-type of healthcare system, VBI has two objectives:

- **to ensure financial access to high-value healthcare services;**
- **to ensure that public resources are well spent (targeting public expenditures towards healthcare that offers "value for public money" – efficient resource allocation).**

3.2. Definition of value

3.2.1. Value in value-based insurance

VBI relates the level of cost sharing to the value of healthcare services. Fundamental in VBI designs is the definition of "value".

Several interpretations of "value" in healthcare are found in literature. In the US literature on VBI, value is often narrowly defined as "the (expected) clinical benefit gained for money spent", corresponding to the concept of incremental cost-effectiveness.[6,12,13] Incremental cost-effectiveness is assessed by means of the incremental cost-effectiveness ratio (ICER). Some authors limit the definition of value in a VBI context to clinical benefit.[14] Both definitions limit the scope of what is considered valuable in healthcare. They are attractive because both the ICER and clinical benefits are quantifiable, but limiting the scope of value in this way may have undesirable consequences. A sole focus on cost-effectiveness, for instance, leads to a situation where treatments such as nicotine patches for smokers who want to quit figure on the list of high-value services amongst treatments such as warfarin for treating nonvalvular atrial fibrillation, angiotensin-converting enzyme inhibitor after myocardial infarction and for diabetes with microalbuminuria, beta-blockers after myocardial infarction and low-molecular-weight heparin for venous thromboembolism.[15] By using cost-effectiveness as the sole criterion for defining value, efficiency in healthcare is considered to be the sole objective of health policy. Efficiency means, in this case, maximising health, given the resources available for healthcare. This approach makes abstraction of potential additional healthcare system objectives, such as equity.[16] Empirical evidence has shown that efficiency and clinical benefit are just two among many criteria for the value of a service.[17]

A broader interpretation of value includes, besides efficiency, criteria such as the disease severity, prevalence, availability of alternative treatments and health (in)equity. It has been demonstrated that the value definition used in real-life decision making resembles more closely this broader definition than the limited definition based on therapeutic benefit and cost-effectiveness.[17] The concept of value used in France for their VBI design is clearly different from the concept used in the US (see text box).[18] The merit

of defining the criteria in such a way is explicitness, especially if these criteria are quantified. However, for criteria that are not quantifiable, it might be difficult to say how these criteria are dealt with in a decision-making process. For example, how does the treatment type determine value in the French approach? Is a preventive intervention valued higher than a curative intervention, ceteris paribus? Transparency can be ensured by justifying, for each criterion, its relative importance and how it has or has not influenced a value appraisal. This kind of transparency is often lacking in decision-making processes.

Example: Criteria used to determine the level of coinsurance of pharmaceuticals in France

In France, coinsurance is determined on the basis of a joint assessment of:

- Safety;
- Therapeutic benefit;
- Place in the treatment strategy (more specifically compared to alternatives);
- Severity of the disease treated;
- Social importance (incidence and prevalence of the condition);
- Treatment type (preventive, symptomatic, curative).

The result is called the "service médical rendu" (SMR). Note that cost-effectiveness as such has no weight in this system.

Cost-sharing amounts to 35% if the SMR is judged to be "major or important"; it is 65% for a "moderate" SMR and 100% for a "weak or insufficient" SMR. Drugs deemed as irreplaceable and particularly expensive are fully covered (e.g. HIV drugs).

3.2.2. Value-based pricing

According to economic theory, the price of a service is not a determinant of its value: a low-priced service can have a huge value and vice versa. The value of a service determines the marginal willingness to pay for the service at each level of consumption (=demand) and in a perfectly competitive market, the price equals the marginal willingness to pay. The market price will emerge through the interaction between supply and demand. In this sense, in a competitive market, there is no interest in value-based pricing.

In healthcare, however, the rules of perfect competition often do not apply. Prices of products are usually imposed by the manufacturer, with little or no room for negotiation: prices are set in a multinational context, with, in addition, a number of barriers to free circulation or parallel import. Prices of services, on the other hand, tend to be the result of negotiations between cartels embodied by the professional defence organizations of providers and public payers. Value-based pricing (VBP) has been advocated as a potentially useful approach to price negotiation. This assertion merits closer scrutiny, though.

The concept of VBP differs from VBI in that it uses value to determine the price, whereas VBI uses value to determine the level of cost sharing. In VBP the societal value of a product or service determines the societal willingness to pay for that product or service and thus its maximum acceptable price, taking budgetary constraints and opportunity costs into account. The budgetary constraints imply that a public payer will not be able to accept exorbitant prices for products or services, even if they would have a huge societal value.

In theory, VBP is particularly relevant if prices can be negotiated during the reimbursement decision process. Hence, the first step in the reimbursement process is to appraise the value. This value determines the maximum societal willingness to pay: in a fixed budget situation, an intervention will be considered value for money if the value gained with the intervention is higher than the value lost due to taking away resources from another intervention to finance the new one. Thus, societal willingness to pay is based on relative value and takes budgetary constraints and opportunity costs into account. The next step is to judge whether the

incremental cost of the incremental value is lower than or equal to the maximum societal willingness to pay for the incremental value. If the incremental cost is higher than the societal willingness to pay, price negotiations will be performed in a VBP system. VBP thus tries to ensure that the price paid does not exceed the socially acceptable price. Sweden uses the incremental cost-effectiveness ratio (ICER) in this way, thereby restricting the value concept to health benefits. France uses the "amélioration du service médical redu" (ASMR) for setting the price. The ASMR considers the added therapeutic benefit of a new intervention as compared with the current standard treatment.

3.2.3. Value in value-based pricing

From the explanation of the concept of VBP, it should become clear that the definition of value may differ between VBP and VBI: while cost-effectiveness can be a value criterion in VBI, it cannot be a value criterion in VBP. In VBP the ICER is a price negotiation tool; it is a measure to be compared to the maximum societal willingness to pay for a unit of health benefit. The ICER cannot be a value criterion itself, as it is determined -among other things- by the price, and used to negotiate on the price. By reducing the price, the ICER can be reduced down to the level of the societal willingness to pay. If the ICER were then also a value criterion, the value -and hence societal willingness to pay- would increase if the price is reduced. This is a circular reasoning.

In VBI the extent to which a service adds to the efficient use of scarce resources *can* determine its value, i.e. when efficiency in the allocation of healthcare resources is considered a value criterion in its own right. Despite the fact that the ICER can be a value criterion in VBI, it should be noted that this criterion can have a high or low weight in the appraisal. A more efficient service can be valued lower than a less efficient service, e.g. because the latter serves a higher medical and therapeutic need. In a VBI system this would imply a higher level of cost sharing for the more efficient service than for the less efficient service.

3.2.4. Issues with value-based pricing in practice

In a perfectly competitive market, the price will emerge through the interaction between supply and demand. For some healthcare services, suppliers will have a monopolistic position, or providers will act as a cartel, meaning that the prices are no longer the result of the demand-supply dynamics on the market. Prices can be set by the monopolist up to the consumers' marginal willingness to pay for the service. It can be argued that this is undesirable for the public payers, who are subsidizing suppliers' profits without having any clear idea about the return on investment paid. In VBP the return on investment is considered unimportant, as long as the price (including the return on investment) does not exceed the marginal societal willingness to pay.

VBP is an attempt to regulate prices in a context of imperfect or absent market competition and absence of transparency about producers' pricing practices. Pharmaceutical companies are rarely, if ever, transparent about the components of the price of a product: production costs of a drug, Research and Development (R&D) costs and return on investment. Transparency is a requirement imposed by the industry on payers (cfr. European Transparency Directive 89/105/EEC of 21 December 1988[19]), but public payers cannot enforce price transparency (yet) on the industry. The public payer -especially in smaller markets- are therefore in the weakest position. Faced with the price for a product that might save lives and pressure from the general public, decision makers often have very little choice as to reimburse a product or service. Insofar as healthcare is recognized as a basic human right in our societies, it becomes then very difficult in practice to put a ceiling to the value of whatever should contribute to restoring health or avoiding death. The fact that neither the end user (the patient) nor the prescriber feel directly financially responsible for the bill and opportunity costs are often not tangible, only adds to the problem. In practice, patients and citizens will pay the bill, through taxes or cuts in other social services and benefits.

In short, it will always be difficult to explain to the public that society is not willing to pay more than x thousand euros to save one more person's life. In this sense, VBP is a weak type of price regulation, keeping the public payer in the weakest position and still granting the freedom to producers to set price in a non-transparent way, pushed to a maximum. Knowing the public payer's marginal willingness to pay, companies will maximize their return on investment by setting the price up to this marginal societal willingness to pay level. De facto, there is often very little price negotiation, and the question is narrowed to the decision whether to reimburse or not, and then, accessorily, to the determination of the reimbursement basis. In the latter decision, cost-sharing considerations unavoidably enter the scene, but failure of VBP also threatens to entail failure of VBI (see next section). Healthcare payers can try to limit budget impact by more or less value-informed mechanisms downstream the reimbursement decision, e.g. through outcome-linked reimbursement schemes ("no cure, no pay"), or by volume-price agreements, but this can no longer be called VBP.

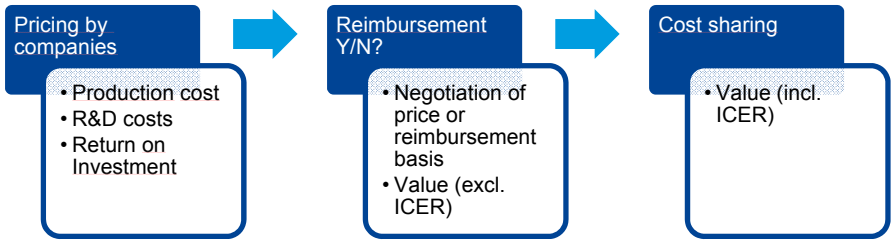
It can be debated whether VBP is an appropriate solution to the problem of lack of transparency about price structures. However, even with full transparency on the price structure of products and services, mechanisms to assess the acceptability of a return on investment are still required.

3.2.5. Value-based insurance when value-based pricing fails

The objectives of VBP and VBI are different. While VBI aims to influence healthcare consumption and/or control public healthcare expenditures, VBP aims to determine a socially acceptable price in situations where regular market mechanisms do not work. As shown in the previous section, VBP is often problematic in the actual real-life situation of a health insurance system. Failure of VBP has also consequences for VBI.

Figure 1 illustrates the criteria applied in different steps of the process for deciding about pricing, reimbursement and cost sharing for pharmaceuticals. Pricing by the companies is based on production costs, costs for R&D, and desired return on investment. The acceptability of a requested price is judged during the reimbursement process. A price is value-based if it is lower than or equal to its societal value.[20] If the requested price exceeds the service's value (e.g., because medical need is insufficient or added therapeutic benefit is limited) given the budgetary constraints, the service should not be reimbursed. A negative reimbursement decision implies a 100% level of cost sharing. If a negative reimbursement decision is taken because it is considered acceptable that patients bear the full cost of the service (e.g. paracetamol), VBP remains useful, as the decision by the public authorities that a product is worth its price, may be informative to patients and providers. In case of a positive reimbursement decision for a product with a value-based price, a decision about the appropriate level of cost sharing needs to be made. In VBI systems, this will be based on a value concept that includes efficiency considerations.

Figure 1 – Value-based principles in a drug pricing and reimbursement process



VBP and VBI are complementary systems in the healthcare sector; the one does not exclude the other. All systems are concerned with paying a socially acceptable price for a product or service. However, VBI does not have the capacity to remedy the price setting problem if VBP fails.

We illustrate this by means of a hypothetical example in Figure 2. Suppose we have a relatively high-valued service. The requested price for the service equals €140, the value-based price €100. We will denote the difference between the value-based price and the requested price as the "price tension". Given the value of the service, the appropriate co-payment (fixed amount) is defined at €20.

If VBP succeeds (first bar in Figure 2):

- The reimbursement basis equals the value-based price, so there is no price tension. The patient pays €20 at the point of service; the public payer pays €80.

If VBP fails, there are three possible decisions with respect to reimbursement:

- Negative reimbursement decision, price equals the requested price, patients bear the full cost (value-based price + price tension) (second bar).
- The public payer pays for the failure to set a value-based price, i.e. the public payer pays the price tension (third bar).
- The patient pays the difference between the value-based price and the requested price. The reimbursement basis is set at the value-based price and the patient pays the patient share + price tension (fourth bar). A reference pricing system where the price of the reference product is based on marginal societal willingness to pay could be an example.

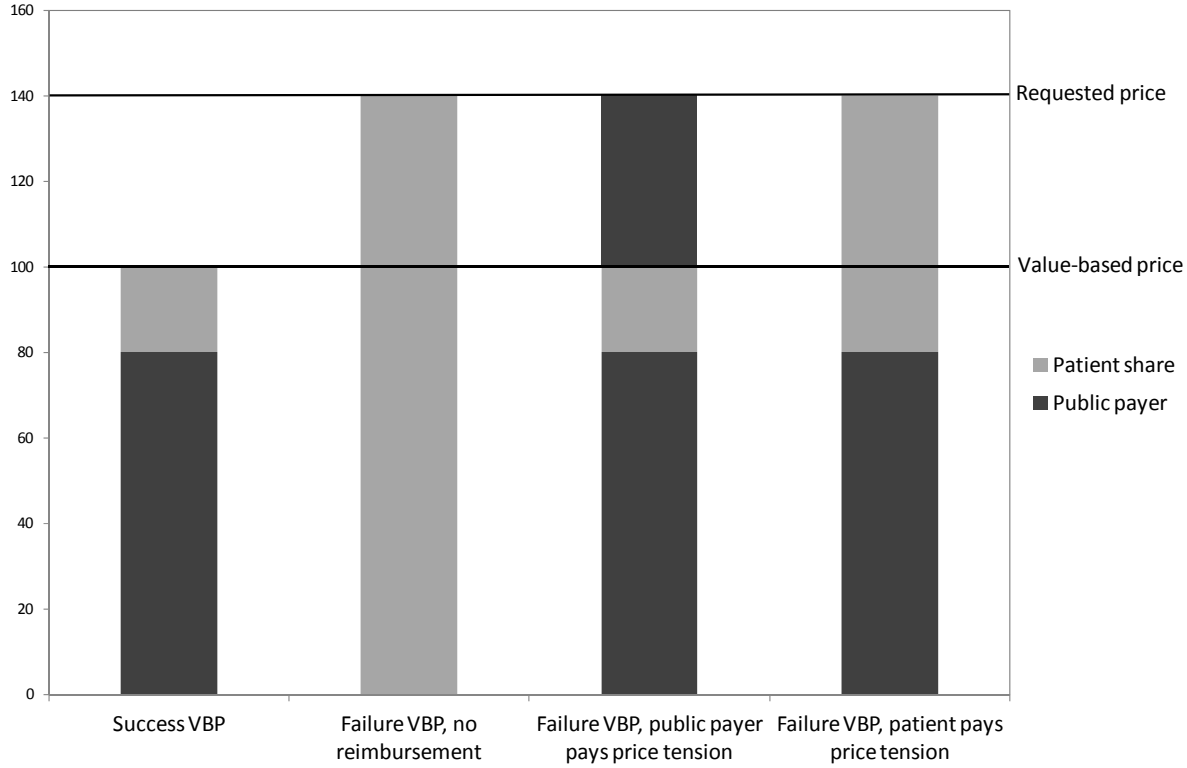
From a VBI perspective, four undesirable outcomes may occur if VBP fails:

1. The service is not reimbursed at all (second bar), implying potential problems of financial accessibility to a high-value service. This violates the first objective of VBI that states that VBI aims at ensuring access to high-value services by limiting the level of cost sharing for these services.
2. The patient pays the price tension over and above the value-based price, besides the patient share in the reimbursement basis. This also violates the first objective of VBI as it increases the total out-of-pocket cost for patients and hence reduces financial accessibility.
3. The public payer pays the price tension, in which case public resources are no longer allocated efficiently. This violates the second objective of VBI that states that VBI aims at ensuring that public resources are primarily allocated to high-value services.
4. Cost sharing can be organised in two ways: either the patient pays a fixed amount (co-payment) or she pays a percentage of the price (coinsurance). In case of a coinsurance applied to the requested price, both the patient and the public payer will pay a part of the price tension. This would violate both objectives of VBI.

Since 19 March 2012, the legal basis for a new reimbursement category Fa/Fb has been established for pharmaceuticals in Belgium. This category contains drugs for which the sum of the coinsurance and the RIZIV – INAMI share is/can be lower than the public price. This could be considered as a category of drugs for which VBP failed. However, the patient does not pay the price tension. Either the distributor, the pharmacist or producer, has to pay the price tension, by which the principle of VBP is again applied. The level of coinsurance is 0% for Fa and 25% or 15% for Fb, as for drugs in category A and B. On 1 April 2012 no single pharmaceutical product was included in this category yet.

In systems without cost sharing, VBI can only take the form of a negative reimbursement decision for low-value services and positive for high-value services.

Figure 2 – Value-based pricing and value-based insurance



**VPB= Value-based pricing*

Value-based healthcare policies

- Healthcare systems are increasingly reflecting on the possibility to apply value-based principles in healthcare policy. While VBI focuses on the level of cost sharing (lower cost sharing for higher value), value-based pricing focuses on the price level (lower price for lower incremental value).

Value-based pricing

- Paying a socially acceptable price for healthcare products and services is important in both systems with and without cost sharing.
- Value-based pricing has been advocated as a possible mechanism for price negotiation, based on societal value and marginal willingness to pay, taking budgetary constraints and associated opportunity costs into account. VBP is an attempt to regulate prices in a context of imperfect or absent market competition and absence of transparency about producers' pricing practices. It is a weak type of price regulation, maintaining the weak negotiation position of the separate public payers compared to producers and non-tranparent pricing practices.

Definition of value in VBP and VBI

- In the context of VBI, value is determined by several criteria, including the severity of the condition (medical need), the effectiveness of existing alternatives (therapeutic need) and its relative effectiveness and cost-effectiveness compared to these alternatives.
- In the context of VBP, value can be determined by the same criteria, except for cost-effectiveness. The incremental cost-effectiveness ratio (ICER) is an instrument to judge whether the societal willingness to pay is not lower than the ICER of the appraised healthcare product or service.

Failure of VBP in a VBI context

- Failure of VBP may entail failure of one or both the objectives of VBI, being improved financial access to high-value services and efficient use of public healthcare resources.

4. TYPES OF VALUE-BASED INSURANCE DESIGNS

4.1. Designs in general

In an ideal world, VBI should determine the level of cost sharing on an individual patient level because the likelihood to benefit from an intervention also varies between individuals. However, such a "personalized" cost-sharing system would not be feasible from an administrative point of view. Three practical VBI designs have been described. The basic principle behind the different types identified in literature, and real-life applications from Belgium, are presented in Table 3 with their advantages and disadvantages (adapted from Fendrick et al.[21]).

Table 3 – Types of value-based insurance designs

	What?	Advantages	Disadvantages
1. Design by service	Patient share reduced for selected high-value services for all patients, regardless of the indication, e.g. angiotensin-converting enzyme inhibitors for patients with congestive heart failure, myocardial infarction or essential hypertension.[10,13,22]	Low administrative burden.	The lack of differentiation between indications can lead to inefficient use of resources. For example, there is strong evidence that the use of cholesterol-lowering drugs for secondary prevention of cardiac events is much more effective than for primary prevention. Reducing patient share for all patients using cholesterol-lowering drugs would hence be less value-based than reducing them selectively for secondary prevention.
2. Design by indication	Patient share reduced for targeted high-risk patients, e.g. patients with a history of myocardial infarction pay less for cholesterol-lowering drugs than patients taking these drugs for primary prevention[21]; asthma patients pay less for inhaled steroids than chronic obstructive pulmonary disease (COPD) patients because inhaled corticosteroids are less effective for treating COPD than for treating asthma.[10]	Better targeting of patients most likely to benefit.	Higher administrative burden as the diagnosis has to be registered for determining the reimbursement level.
2.1. Subtype 1 **Design by medical need (considering condition severity without treatment)**	Patient share reduced for services targeting conditions with a severe health outcome if not treated (e.g. chronic heart failure).[6,10,13,22]	Takes medical need into account (though not therapeutic need*). Targets patient share reductions towards indications with the strongest evidence of absolute benefit (compared to doing nothing).	No association between the level of patient share and the expected level of benefit for individual patients (all patients with the same condition pay the same patient share). Focus on efficacy or effectiveness compared to “doing nothing”. No account taken of the effectiveness of existing treatments for the same indication (therapeutic need*).

	What?	Advantages	Disadvantages
			Patient share for new treatments with limited but clinically relevant incremental benefit compared to existing treatments for a life-threatening disease are lower than for new treatments with high incremental benefit compared to existing treatments for non-life-threatening diseases.
2.2. Subtype 2 **Design by therapeutic need (considering condition severity after current standard treatment)**	Patient share reduced for treatments with highest incremental value compared to existing treatments and targeting diseases that are still severe under current standard treatment.	Takes both medical and therapeutic need into account*. Better targeting to patients with highest likelihood to benefit. Ability to modify patient share according to healthcare innovations, e.g., while the first insulin analogue could be reimbursed at 100% because of the severity of diabetes without treatment, the second or third insulin analogue, adding relatively little to patients' outcomes as compared to the existing product but more expensive, could involve a patient share (keeping the first insulin analogue available at no cost for the patient).	High information needs: assessment of relative medical and therapeutic need*, safety, incremental effectiveness, cost-effectiveness for all products and services.
3. Design by participation	Patient share reduced for patients who actively participate in a disease management programme (DMP) or similar incentive programme.[10]	Incentive for participation in evidence-based DMP (better follow-up, integrated care).	Requires physicians' awareness of the existence of a DMP. Both physicians and patients should be informed.

** Therapeutic need depends on the availability (or not) of effective alternative treatments. When an effective alternative treatment is available, the therapeutic need for a given indication is lower than when no alternative treatment is available for that indication. Medical need is related to the severity of a health state without treatment. The more severe the condition is if untreated, the higher the medical need.*

VBI by participation is in principle the most encompassing approach. It is different from the other VBI designs in that cost-sharing reductions are based on a discrete decision to participate or not in the DMP. Participation gives a right to cost-sharing reductions. The extent of the reduction may differ, though, between services included in the DMP. Individual services included in the DMP may indeed have different relative values. Hence, the cost-sharing structure will depend on the type of the service and the value of the service. Ideally, but not necessarily, evidence-based practice guidelines should take all aspects that determine the value of the healthcare services into account. Most guidelines are limited, however, to clinical effectiveness. If clinical practice guidelines do not consider cost-effectiveness, and cost-effectiveness is a value criterion in VBI, the level of cost sharing may sometimes be at odds with the recommendations in the guidelines; i.e. a recommended treatment may be associated with a high level of cost sharing. This high level of cost sharing for patients participating in the DMP will, however, still be lower than the level of cost sharing for that same service for patients not participating in the DMP.

For **VBI by indication**, we make a distinction between VBI by medical need (subtype 1) and VBI by therapeutic need (subtype 2). The implications of this distinction merit some further explanation.

In subtype 1, treatments for severe conditions are typically valued higher than treatments for less severe conditions, even if the outcome in terms of health is the same, ceteris paribus. In VBI by **medical need** the treatment for the severe condition will then be associated with a lower level of cost sharing. This design thus ignores the effectiveness of existing treatments (therapeutic need), while this is an important determinant for the value of a treatment. A new treatment for a severe condition that is only slightly better than the existing treatment will usually not be considered as valuable as the very first treatment for that condition. For example, the first insulin analogue coming to the market will be considered more valuable than the 7th, with a marginal incremental benefit compared to the 6th. Of course, an alternative approach could be to stop or limit reimbursement of the existing treatment.

VBI by **therapeutic need** (subtype 2) solves this issue by valuing services by their *incremental benefit* as compared to current standard treatment instead of by their total benefit. There are, however, a number of issues with the VBI by therapeutic need design. The first issue is of practical relevance. What happens if the current standard treatment does not work for particular patients and patients need to follow the new treatment? For these patients the principle of VBI by therapeutic need could be maintained. The therapeutic need of these patients will be considered higher and therefore their cost sharing for the new treatment will be lower than for patients who currently are eligible for the standard treatment. The only note of caution here is that the total level of cost sharing should not differ between patients who fail on standard treatment and patients who succeed on standard treatment, in order to be consistent with the principle of VBI by indication. In other words, the principle requires that patients with the same indication pay the same patient share for their treatment, irrespective of whether they need the standard treatment or the new treatment. The approach presumes that the provider only applies the new and more expensive treatment if the standard treatment failed or will certainly fail.

The second issue is more fundamental and relates to the acceptability of VBI by therapeutic need when it concerns services for severe conditions (high medical needs). It could be questioned what is the best decision for a service with only a marginal incremental value targeting a high medical need in view of the objective of VBI of steering behaviour towards high-value healthcare. Imposing a higher cost share on this treatment may be considered unacceptable, as it might give the wrong signal to the patient that treatment is of low value and therefore not needed. A patient who is unaware of the lower cost share for the standard treatment for his/her condition, might move away from treatment altogether. Moreover, in case of very expensive services, the cost sharing may become very high, which may be considered unfair and impractical. The political question is then whether it would not be better to take a negative reimbursement decision for the service in the first place. A choice has to be made between the societal acceptability of charging (higher) cost sharing for high medical needs but low incremental value versus the non-reimbursement of these services altogether.

The application of a VBI design by medical need requires an operational definition of condition severity. Several approaches for measuring the severity of disease have been suggested in literature. These have been summarized in KCE report 147.[17] One approach could be to define disease severity in terms of QALYs lost. This implies a continuous scale, which might not be practical. A practical approach could be to define categories of condition severity, e.g. life-threatening, severely debilitating, moderately debilitating and mild, and subsequently classify treatments in one of these categories[d]. It should be noted that the severity of a specific condition may depend on the overall health of patients. For example, nausea may be considered a mild condition for a person otherwise in good health, but a severe one for a person with cancer on chemotherapy. This means that the same intervention might have a different value depending on the population in which it is used. For example, anti-emetics for treating nausea can be low value in populations with occasional nausea and high value in patients with cancer.

4.2. Value-based insurance designs in function of the type of service

4.2.1. One size does not fit all

Different types of VBI designs can co-exist within one healthcare system. It is unlikely that one design will fit all. A balance has to be made between feasibility and effectiveness of the system. The most optimal solution (determination of the patient share on an individual level) is not feasible. The optimal level of differentiation by individual will depend on the cost of the treatment, the risk of inefficient or inappropriate use and the number of indications. As such, it is more efficient to implement an individualized VBI approach for high-cost orphan drugs than for GP consultations.

In the previous sections, we often did not differentiate between services and products (drugs and medical devices). Value-based insurance can be applied to both; there is no theoretical rationale for using VBI only for pharmaceuticals and not for healthcare services.[23] Nevertheless, natural experiments with VBI have up till now focused mainly on prescription drugs for chronic diseases.[24] The focus on chronic diseases is related to the clinical and economic importance of these diseases. The focus on drugs may be explained by the fact that drugs always target a specific indication or a limited number of indications, unlike many healthcare services. For example, specialist consultations or medical imaging techniques can be applied for a wide variety of indications. The practical implementation of value-based cost-sharing differences by indication then becomes more complex, unless the appropriate use of these services can be defined in disease management programmes. Another reason for the focus on pharmaceuticals might be the already well developed assessment mechanisms for pharmaceutical products. Most countries have developed drug reimbursement systems based on scientific assessment and appraisal procedures. The evidence base for determining the (clinical) value of a pharmaceutical product for a specific indication is often stronger than the evidence base for determining the value of, for example, a GP consultation for a specific indication.

A system that aims to apply value-based insurance principles will have to combine several types of VBI for several types of services.

Table 4 gives an overview of possible (combinations of) VBI designs for different types of services.

[d] Although the severity of a condition can vary between individual patients, a feasible approach from an administrative point of view would require to define the severity of a condition based on averages.

Table 4 – VBI designs by type of healthcare service

Service type	Type of VBI* design
Pharmaceuticals/devices	VBI by indication (therapeutic need) VBI by participation in a DMP**
GP consultations	VBI by service VBI by participation in a DMP
Specialist consultations	VBI by indication VBI by participation for specialist consultations included in a DMP
Technical acts/interventions	VBI by service VBI by indication VBI by participation for acts/interventions included in a DMP
Screening programmes	VBI by participation
Vaccination programmes	VBI by participation

**VBI= Value-based insurance*
***DMP= disease management programme*

In general, it should be noted that for all types of services, VBI by service and VBI by participation could co-exist. This means that cost-sharing differentiation by, e.g., indication, can be combined with cost-sharing differentiation by participation. Patients participating in a disease management programme (DMP) are then eligible for an additional cost-sharing reduction, on top of a potential cost-sharing reduction because of their condition. Patients suffering from the same condition but not participating in a DMP, then fall under the baseline cost-sharing rules, which may be value-based by service or by indication.

The importance of combining the two mechanisms lies in the possibility to define only appropriate volumes of use of the specific services in the DMP. As such, patients are eligible for cost-sharing reductions by participation only for the services and volumes of these services included in the DMP. Suppose a DMP defines that one specialist consultation a year is needed, patients will get the cost-sharing reduction by participation for one specialist consultation, but will have to pay more for additional consultations at the specialist's. In case of a combined VBI by indication and VBI by participation, the level of cost sharing by indication will apply for the additional consultations.

For GP consultations, it seems more appropriate and feasible to apply a VBI design by service (possibly in combination with a VBI design by participation), as differentiation by indication would induce an unacceptably high administrative cost. For technical acts or interventions, the most appropriate design depends on the type of act or intervention and the trade-off between the costs and benefits of differentiation by indication. For example, for common laboratory tests (clinical biology), VBI by service will probably be more appropriate than VBI by indication. For expensive and specific tests, however, VBI by indication might nevertheless be a desirable option. Similar considerations apply to medical imaging, which is also characterised by a variety of tests, ranging from relatively cheap low-tech techniques to expensive high-tech techniques requiring a specific expertise.

4.2.2. Belgian examples

Belgium currently applies several VBI designs for **pharmaceutical products**. The basic design consists of VBI by service, whereby drugs are classified in drug reimbursement categories based on medical need and defining the coinsurance for the drugs in that category (see Table 1). Examples fitting into this general design include diabetes type 2 drugs, reimbursed in category A (0% coinsurance) and asthma drugs, reimbursed in category B (25% coinsurance or 15% for patients with preferential reimbursement). On top of this general design, Belgium applies VBI by service/product (e.g. vitamin B1 supplements), by indication (e.g. for statins[e], cfr. Table 2) and by participation in a disease management programme (e.g. fully reimbursed GP and specialist consultations). Policy tools are developed to ensure that VBI rules are followed for these specific cases. An example of such a tool is the prior approval by the supervising physician of the sickness fund.

For **physician consultations and technical acts**, fees are negotiated in the National Commission of Representatives of Physicians and Sickness Funds of RIZIV – INAMI (the so-called "Medicomut"), often in the absence of evidence that is relevant for services' value. Coinsurance rates are applied to these fees without much initial discussion about the precise implications for the patients in terms of affordability.

The **care trajectory** for diabetes 2 can be classified as a VBI mechanism by participation in a DMP.

[e] It is impossible to say, based on simple observations of the rules for reimbursement for statins, whether these rules are based on therapeutic need or on medical need.

The more targeted the VBI design to high-value healthcare services, the higher the administrative burden and information requirements. The less targeted, the higher the possible inefficiencies. For identifying the most appropriate VBI approach for a specific healthcare service, the cost of better targeting needs to be balanced against its benefits.

VBI by participation in a disease management programme is administratively feasible but requires the development of such programmes for several diseases. For services not included in such programmes, the most appropriate VBI design will depend on the services' cost, their risk of inappropriate use and their number of indications. Several VBI designs can co-exist in one healthcare system.

In case of multiple indications for one service, a value-based cost-sharing level should ideally be defined per indication.

Medical and therapeutic need are determinants of a service's value. Considering medical need alone implies ignoring the value of available alternative treatments.

For a high-value service with an unacceptably high incremental cost-effectiveness ratio, there are two options: either a negative reimbursement decision or a positive reimbursement decision where the reimbursed amount equals that of the comparator and the patient (or someone else, e.g. pharmacist or distributor) pays the difference between the price of the new service and that of the comparator. The choice between the options is a societal choice and depends on the acceptability of a high patient share for marginally better treatments.

For the practical application of a VBI by disease severity, an operational definition of severity is needed. Classification of conditions into categories of severity seems to be the most practical approach.

There is no theoretical rationale for limiting VBI to pharmaceutical products only. VBI by service and VBI by indication can be combined with VBI by participation in a disease management programme. Such a combination has the advantage of limiting certain cost-sharing reductions to the volumes defined in the DMP. Services consumed/used beyond those identified in the DMP or by patients not participating in the DMP might still be differentiated by indication and/or service if considered valuable.

5. ISSUES IN VALUE-BASED INSURANCE

5.1. Value-based insurance and social protection

In the broad definition of value, equity in healthcare is a determinant of societal value. Differentiation of cost sharing for reasons of social protection can therefore be considered as being part of VBI. VBI might have an impact on patients' disposable income after (necessary/high-value) healthcare. This, in turn, might impact upon patients' health. Thomson et al. (2010) argue that European countries generally provide financial protection to poorer households and to people with the greatest health needs (e.g., the chronically ill).[11] These social protection mechanisms (partly) take away the financial barriers to access, which is essential for the treatment adherence of these patient groups. Especially for the patients with the greatest health needs this is important as they are the ones most likely to benefit from healthcare.

At the same time, a VBI design can be implemented separately from social protection mechanisms, in which case the consequences of the VBI design for several socioeconomic groups have to be assessed to ensure equity is maintained (or improved). For example, a KCE study examined the impact of the introduction of a reference price system for drugs in Belgium on the consumption of the cheapest drugs by different socioeconomic groups. In this system, patients have to pay the price tension between the cheapest drug and the brand drug. The question asked was whether this (VBI) system would not harm (in terms of financial accessibility) the most vulnerable groups of society, as they might be less well informed by the measure. KCE identified no underuse of cheaper drugs in the less privileged socioeconomic groups as compared to the general population.[25] Even a slight inverse tendency was observed. Therefore, the reference price system was considered promising in terms of overall equity, defined as financial accessibility.

Many social protection measures are taken on top of value-based cost-sharing measures, besides the social protection measures which are part of them. An example is the Belgian system of drug reimbursement categories. On the one hand the categories (should) reflect the value of products (VBI), e.g. life-saving chronic treatments are fully reimbursed. This is a protection mechanism directly integrated into the definition of the value-based cost sharing level. On the other hand, reduced cost sharing for specific vulnerable population groups (i.e. preferential reimbursement) is foreseen within each category (social protection against catastrophic healthcare expenditures). This is an example of a social protection measure taken on top of the defined value-based cost sharing level. Both fit, however, within the concept of VBI. The same applies to the maximum billing system (MAB). This system implies full reimbursement of the patient share once a specific, income-related ceiling of co-payments and coinsurance rates for healthcare is reached. The implication of the MAB and preferential reimbursement is that the same treatment might cost less for some patients than for others. This may lead to the situation where high-value services cost more in absolute terms for high-income patients than some low-value services for low-income patients. This is then a deliberate choice in view of the social protection against catastrophic income loss due to illness in low-income patients.

Given a broad definition of value, including equity as a value criterion, social protection measures directly fit *within* the principles of VBI.

5.2. Value-based insurance and coinsurance versus co-payment

VBI asks for fixed co-payments, defined independently from the price of the product or service. Firstly, high-value healthcare products (drugs and devices) are often priced higher than low-value products, especially in a VBP context. Coinsurance, which defines the patient share as a % of the price, would cause the more expensive treatments, which are also more valuable, to be more expensive to the patient. This conflicts with the first principle of VBI that high-value interventions should be less costly for the patient than low-value services.

Secondly, treatment costs tend to increase with every new intervention with an incremental therapeutic benefit (better interventions are rarely less

costly[f]). With coinsurance, a treatment with an incremental therapeutic benefit would become more expensive to both the public payer and the patient. It can be justified that the patient's out-of-pocket payment increases if the incremental therapeutic benefit is not considered valuable from a societal point of view, but it cannot be justified that the public payer's payment increases for a treatment that has no added societal value. This would conflict with another basic principle of VBI, i.e. that public resources should be allocated such that the highest value is obtained for society (the efficiency requirement).

Belgium applies coinsurance to drug reimbursement categories, which are defined in function of the severity of the targeted condition. Category A corresponds to 0% coinsurance. The combination of coinsurance with this type of VBI by medical need implies that the patient will pay more for every better and more expensive drug accepted for reimbursement, unless the drug falls in category A. At the same time, patients taking drugs in category A keep paying nothing, irrespective of how marginal the incremental value of the new intervention is. This is purely due to the focus on medical need, ignoring actual therapeutic need (see paragraph 4.1).

The risk of ever increasing out-of-pocket costs for new drugs falling outside category A is reduced by the application of a ceiling co-payment. This ceiling reduces the undesirable inflationary effect on patients' out-of-pocket costs due to the application of coinsurance.

The system of fixed categories, with fixed coinsurance rates instead of co-payments may also be problematic in case of VBI by therapeutic need. The first insulin treatment for diabetes type II for instance, would most likely be in the lowest coinsurance category, as it concerns a life-threatening disease. The next generation of insulin analogues will have a lower value than the first generation, which could be an argument to put them in a higher coinsurance category. However, with coinsurance the amount reimbursed by the RIZIV – INAMI depends on the price of the product. It can thus happen that, in absolute terms, the reimbursed amount of a lower-valued product is higher than the reimbursed amount of a higher-valued product. This conflicts with the VBI objective of efficient use of public healthcare resources (objective (2), see 3.1).

Another consideration related to VBI and coinsurance are price differences between services that might not necessarily be explained by differences in value. The clearest example for Belgium is the price (honorarium) of specialist consultations, which vary significantly between specialists. The application of a single coinsurance percentage to all specialist consultations induces cost-sharing differences which are not justified by differences in value. Fixed co-payments for all specialist services avoids this problem. If coinsurance is to be maintained, high-cost services that are considered to be of high value should have a lower coinsurance rate than low-cost services that are considered equally highly valuable, in order to obtain the same amount of cost sharing for both equally valuable but differently priced services.[26]

VBI asks for fixed co-payments, defined independently from the price of the product or service. VBI is not compatible with coinsurance, because coinsurance might lead to different out-of-pocket costs for equally valuable but differently priced services. VBI is also incompatible with the current Belgian drug reimbursement categories with fixed coinsurance rates, as they may lead to higher public expenditures for products with an incremental health benefit that is considered not sufficiently valuable from a societal point of view to justify reimbursement in the category of the current standard treatment.

Applying a fixed coinsurance level on physician consultation and visit fees is inconsistent with the principles of VBI.

[f] This may be due to value-based pricing approaches, as a consequence of which providers of health services and producers of health products know they *can* ask a higher price for better interventions.

5.3. Conditions for implementing value-based insurance

Critical success factors for VBI to increase the efficient use of healthcare resources are: availability of evidence to allow an appraisal of the value of healthcare services, efficient targeting for limiting cost sharing for high-value services and increasing cost sharing for low-value services, patient information, and audits of the appropriate use of the system.

5.3.1. Evidence on the value of healthcare services

The implementation of a VBI scheme requires knowledge on the relative value of a wide range of healthcare services.[10,23] Currently, data are still insufficient to inform many required analyses. For some services, such as drugs, the application of VBI principles should be easier than for others, e.g. medical imaging or physician consultations. There is a clear specification of the product-indication combination in the case of drugs, data requirements for a drug reimbursement request are extensive and appraisal of the value of products is already embedded in current drug reimbursement processes. VBI by indication seems to fit well within these decisional processes for drugs, whereas this fit may be much less present for physician consultations, for instance.

Several authors argue that priority should be given to the evaluation of high cost/high expenditure services.[10,23, 27] Health technology assessment (HTA) could play a role in providing the relevant evidence for determining the value of services.

It is rather rare that the value of a treatment is clear-cut from the start, after initial assessment of the effectiveness and cost-effectiveness of the service or product. More often, there is remaining uncertainty about effectiveness, cost-effectiveness or the extent of the target population (i.e. objective assessment elements), or about the relative importance of the incremental benefits of the service or product as compared to treatments in other disease areas (i.e. appraisal elements determining the societal value of the service).

For drugs and devices for which there is insufficient or insufficiently strong evidence of effectiveness, the value could be downgraded (i.e. lower levels of evidence are associated with lower value and hence higher cost sharing). It should be emphasized, though, that this implies that patients carry the full responsibility of the lack or weakness of the evidence. Such a strong position should be supported by society before its implementation can be considered. A possible alternative to divert the cost of weak evidence or uncertainty to patients is to limit reimbursement to use within the context of a clinical trial (coverage with evidence development) or not reimburse at all.[26]

For pharmaceutical treatments that are used beyond their boundaries of established effectiveness, value determination could be limited to their use according to the label approved by the Food and Drug Administration (FDA) or the European Medicines Agency (EMA), or to their use within an evidence-based care pathway. This used to be the approach adopted in Belgium until 29 March 2012; i.e. drugs could only be reimbursed for indications included in the EMA label. This legal clause has now been removed, meaning that in principle also off-label indications could be reimbursed. Reimbursement conditions can, however, always be imposed. For healthcare *services* (e.g. medical imaging, radiotherapy) value determination could be limited to evidence-based indications.[26]

For drugs whose effectiveness varies according to disease severity or genotype, value could be defined by the results of a diagnostic test of susceptibility (ex ante evidence of value) or a biomarker indicator of response (ex post evidence of value).[26] Both approaches are implemented for some drugs in Belgium. *For services*, this is less common. The reduced patient share for visits to the emergency department (ED) if preceded by a referral from the GP as compared to ED visits not following a referral, could be considered as an example of this approach for such visits.

For surgical procedures, it has been suggested to define value by provider quality, using criteria similar to those used to define centres of excellence (e.g. working according to evidence-based guidelines).[26] The fundamental question with this approach is -as for drugs with insufficient evidence of effectiveness- whether it is ethically acceptable to let patients pay more for lower-quality procedures. As quality of care is one of the main objectives of healthcare systems, it might be more appropriate to develop supply-side incentives for better quality of care rather than to try to solve a problem of healthcare quality through patient cost sharing.

5.3.2. Efficient targeting

The value of an intervention can vary across indications (e.g. bevacizumab for colorectal cancer versus non-small cell lung cancer), according to its place in the treatment path (e.g. statins for primary versus secondary prevention) or across patients (e.g. HPV vaccination for patients at risk (sexually active people without HPV infection) versus patients not at risk (people with past HPV infection)).[12,28] Ideally, VBI designs take this variability into account.[12,23]

In the most extreme case, cost sharing would be differentiated by individual.[29] Although this adds complexity to the system, several authors consider this to be feasible given the increasing opportunities provided by information technology.[14,23] Also in case of personalised medicine, individualized VBI would become feasible for specific interventions.

A completely individualized determination of the level of cost sharing for all products and services is probably not feasible. An average estimate of the severity of a disease and the expected benefit of a treatment will probably always be used to some extent. Moreover, it can be questioned how far such a system would have to go and to what extent it is ethically acceptable. Should unhealthy behaviour be penalized (e.g. should a former alcoholic pay more for a liver transplantation than someone else?) and/or healthy behaviour be rewarded? If such information is collected, what are the associated risks (e.g., use for other purposes)? Concerns about privacy protection might also be raised.[6]

In a context of VBI by condition, de Souza et al. (2011) consider the example of bevacizumab, a drug approved for metastatic colorectal cancer and for non-small cell lung cancer (NSCLC). They use a narrow definition of value, based exclusively on cost-effectiveness. In case of metastatic colorectal cancer, a treatment with bevacizumab costs $42 400 and increases life expectancy by 4.7 months (ICER= $9 000 per month of life gained). In NSCLC a bevacizumab treatment costs $49 600 and increases life expectancy by 2 months (ICER = $24 800 per month of life gained). If both diseases are considered equally severe and all other relevant decision criteria are considered equal between the diseases -an assumption that can only be held under a narrow value definition-, it could be argued that cost sharing for bevacizumab should be higher in case of NSCLC treatment than in case of metastatic colorectal cancer treatment.[28] The authors argue that in a VBI design -in this case purely based on incremental cost-effectiveness of the drug- the patient should be held financially responsible for the difference between the ICER of the treatment for NSCLC and the ICER threshold value (set equal to 300% of a country's per capita gross domestic product (GDP)).[28] This would mean that from the point of view of the society implementing this strategy, the public payer is ready to pay the amount up to the ICER threshold value. The general caveats of the ICER threshold value approach have been discussed extensively in KCE report 100 and remain valid.[16] For example, the ICER threshold value approach makes no distinction between who receives the health benefits. This assumption may raise serious equity concerns. In addition, the earlier mentioned undesirable impact on cost sharing of a failure to set a value-based price also applies. In the given example, the price of bevacizumab should be lower to be value-based. If not, either bevacizumab for treating NSCLC should not be reimbursed or the public payer or patient pay the price tension.

5.3.3. Data requirements

Efficient targeting, even on group level, requires extensive data collection and accurate use of the existing databases. This may entail important administrative costs and raise important ethical questions about the acceptability of such a detailed data registration. For some VBI designs (e.g. limiting specific drugs to specific patient groups), data are needed about risk factors of patients. This will be more difficult for some (sensitive) characteristics (e.g. blood pressure, smoking habits) than for others (e.g. age).[30] Only in case of VBI by service, where the level of reimbursement is equal for all patients using the service irrespective of their underlying risk, this level of detail is not required. Chernew et al. (2007) state that claims data currently contain insufficient evidence to differentiate between high- and low-value services, because data about risk factors are not included.[6] Developing accurate mechanisms for identifying the patients who will benefit most from a service clearly is a significant administrative and ethical challenge.[30] Improved information systems that tie together electronic medical records, evidence-based practice guidelines, HTA information and reimbursement data should help facilitating targeting.[31] The sophistication and cost of such systems depends on the intended level of clinical targeting.[30] In the meantime, the initiative to apply lower cost sharing to particular patients could be left to the physicians who do have the necessary information about their patients. Of course, auditing will be required in such a case to avoid abuse of the system.

A possible concern related to this data collection and use of databases is related to the privacy of patients.[6] If insurers have to reimburse more or less depending on the indication or other patient characteristics, they need access to this clinical information. This might pose problems for the protection of the privacy.

In Belgium, this has been solved for some specific drugs by the requirement to obtain approval for prescription from the supervising physician of the sickness fund of the patient based on the clinical indication and the intended treatment. If this approval is obtained, the patient is entitled to a lower level of cost sharing (or no cost sharing at all).

5.3.4. Auditing

VBI might require a form of auditing in order to avoid over-reporting of conditions giving access to high-value services.[23] Patients or providers might be encouraged to misreport information to qualify for the reduced patient share.[6,32] This potential incentive should be monitored. Mechanisms for reducing or avoiding this strategic behaviour might then have to be developed.

In Belgium, a priori and a posteriori approval of medication use, giving access to reimbursement or to a lower cost-sharing category can be considered as a measure to control appropriate use of the VBI system.

5.3.5. Patient and physician information

Whenever there is a *choice* between a high-value service and a low-value service for treating the same condition, patients as well as healthcare providers (e.g. physicians) ought to be informed.[33,34] Patients cannot be supposed to be aware of the alternative treatment strategies and their associated out-of-pocket costs and physicians should be aware of the financial implications for their patients of using a specific treatment if alternatives are available. VBI by participation in a disease management programme -i.e. eliminating or reducing cost sharing if patients participate in a disease management programme- might help patients and providers identifying the highest-value services.[10]

In Belgium, for instance, cost sharing has been eliminated for services included in the disease management programme for diabetes type 2 patients and for chronic renal failure patients. Development of more evidence-based disease management programmes, consisting of high-value services, is desirable.

Related to patient information is *public* information about the mechanism and principles of VBI itself. In a design where the level of reimbursement of a particular service can vary between indications, patients might object to being charged more for the same service than others.[6] The general public must be aware that a relationship is defined between the relative value of a service and the level of cost sharing.

5.3.6. *Integrated approach*

Integration of VBI principles in the complete management of a disease is preferable. Clinical practice guidelines include recommendations on how to manage a particular condition. However, some will and others will not incorporate all relevant value criteria in their recommendations. In US literature, where very often a narrow definition of value is used, focussing mainly on cost-effectiveness, it is argued that *if* clinical practice guidelines incorporate cost-effectiveness considerations, VBI should be applied to all items in the guideline.[32] However, as emphasized before, this narrow definition is not the one applied in most European systems.

If the guidelines do not incorporate all relevant value criteria, VBI can still be applied but will in practice lead to a reduction in compliance with the guidelines. A physician who can choose between a recommended treatment that is not reimbursed because it is considered of low incremental value, might prefer to treat his/her patient with another treatment that is reimbursed but not recommended as the best treatment in the guidelines.

Whenever VBI is considered in a healthcare system, it should be integrated as a basic principle for cost sharing in all domains of the healthcare sector. If not, VBI may fail to reach its objective of reducing the use of inefficient healthcare and promoting the use of efficient healthcare.

Conditions for implementing VBI are:

- **Availability of the required evidence to allow the determination of the value of healthcare services;**
- **Efficient targeting of patients for low or high cost sharing (i.e. identification of patients for whom a service provides high value and patients for whom a service provides low value);**
- **Privacy protection;**
- **Extensive data collection and registration;**
- **Auditing of appropriate use of the system;**
- **Patient and provider information about differences in cost sharing for similar services;**
- **Public information about the principles of VBI;**
- **Integration of VBI in the entire healthcare system as a principle of cost sharing.**

5.4. Public acceptance and support for value-based insurance

Empirical evidence from the US shows that overall the public is willing to pay out-of-pocket for less effective interventions if healthcare's affordability is at stake.[27] However, the role of scientific evidence as the sole criterion for determining the level of coverage is not generally accepted. Other criteria, such as affordability for low- and middle-income patients, the purpose of the treatment (life-saving, restoration of normal functioning and prevention of illness or disability) were found to be even more important than clinical effectiveness in several empirical studies performed at the Centre for Healthcare Decisions in the US. Effectiveness and cost-effectiveness were third and fourth in the list of relevant criteria. Healthcare priorities, as defined by the public, were also found to be an adequate criterion to determine the level of cost sharing. About 80% of the respondents to the surveys thought that patients should pay more to treat low-priority medical problems than high-priority medical problems. This

refers to the relative importance of the medical and/or therapeutic need criterion. Finally, the public found increases in cost sharing for low-value healthcare services more acceptable than eliminating coverage altogether.[10,27]

Factors that limited the acceptance of value-based cost sharing were physician's recommendations. It seems less acceptable to increase cost sharing for services that are recommended by the patient's physician, even in cases where the scientific evidence suggests lower value. This points towards the importance of adequate information about the proven effectiveness of treatments to patients.

Because people vary in how they value healthcare services, it is important to find a societal balance. The definition of the societal value of healthcare interventions requires a transparent and explicit framework, and the involvement of all stakeholders affected by the coverage decision.[17]

Empirical evidence shows that the general public is willing to pay more out-of-pocket for less effective services. However, besides scientific evidence, also other criteria are felt to be important in determining the level of cost sharing for healthcare services, including the medical and therapeutic need (severity of the disease being a major consideration). It is considered less acceptable to vary the level of cost sharing according to value if a product or service has been recommended by a physician.

6. IMPACT OF VALUE-BASED INSURANCE

6.1. Expected benefits of value-based insurance

The impact of VBI is expected to be determined by the effectiveness of the services targeted, the level and precision of the targeting, the magnitude of the cost-sharing changes and patients' responsiveness to price changes (price elasticities).[13] In this paragraph, we discuss how VBI could theoretically impact on adherence, healthcare expenditures, and access to healthcare. The next paragraph describes the results of a number of natural experiments with VBI in the US. The last paragraph illuminates some methodological issues which may be encountered in the evaluation process of a VBI design, with a focus on the DMP in Belgium.

6.1.1. Impact on adherence

VBI can have an impact on adherence if the cost of a treatment for the patient is a reason for non-adherence. The demand for treatment may partly reflect treatment adherence, but the analogy is certainly not perfect. Adherence refers to the patient's starting or continuing the prescribed treatment for his/her condition. The demand reflects the consumption of services at each price level. On the one hand, there are many other determinants for patient adherence besides the patient's cost share and their relative importance for treatment adherence is rather unclear.[35] On the other hand, treatment prescriptions are not the only determinant for the demand for healthcare. Therefore, the demand of healthcare is only a proxy for adherence.

Assuming that the demand is a good proxy for treatment adherence, the price elasticity of the demand will determine the extent of the impact of VBI. For services with a high price elasticity the impact will be bigger than for services with a low price elasticity. Given the empirical evidence that cost sharing reduces both inappropriate and appropriate healthcare utilization, because patients have insufficient information or are unable to distinguish between appropriate and inappropriate care,[6] with VBI by service, a decrease in cost sharing for high-value services in VBI, may also increase inappropriate use of these high-value services. VBI by participation in a disease management programme (DMP) or VBI by

indication reduce this effect. However, even in this case, the determination of the optimal cost sharing level should take the price elasticity of the demand into account. For example, a DMP might include services that individually are of low value but nevertheless important for the effectiveness of the complete programme. It would not be wise to apply a relatively high level of cost sharing to these services if the price elasticity of the demand for these services is high (i.e. patients would reduce their consumption of these services drastically because of the patient share). The lower consumption of these services would jeopardize the effectiveness and hence the value of the DMP.

In conclusion, the consideration of the price elasticity of the demand for healthcare services is important to avoid that patients do become non-adherent to appropriate treatment for financial reasons. It has been recommended in literature to provide also other financial and non-financial incentives to increase patient adherence to high-value health services and lifestyle changes. Financial incentives might include cash transfers, rebates of insurance premiums for patients with good outcomes or in-kind transfers.[35] Non-financial interventions might include improved social support, practical tools (calendar packaging with reminders), pharmacist interventions, cognitive behavioural therapy, etc.[36-40]

6.1.2. Impact on healthcare expenditures

In the US, a frequently asked question is to what extent VBI will lead to increases in overall health insurance expenditures. High-value services, i.e. services considered cost-effective according to the narrow value definition applied in the US, are usually not cost saving for the healthcare payers' point of view.[30,35] It is therefore concluded that the reduction of cost sharing for high-value services could result in important increases in healthcare expenditures if it is not accompanied by an increase in cost sharing for low-value services.[6,10,23,30] However, this is the short-term perspective.

The untested hypothesis for the long term, is that health insurance expenditure increases will be lower, the better the targeting of the patients that will most benefit from a given intervention. It is assumed that the increase in costs will at least partly be offset by savings through reduced hospitalizations and emergency room visits, and even if the costs are not completely offset by the savings, resource use will be more efficient. This effect will be higher when the underlying risk of an expensive adverse event is high, consumers are responsive to a lower patient share and the service targeted for lower cost sharing effectively prevents the adverse outcome.[13] Effective targeting of patients entitled to lower cost sharing is therefore crucial.

A narrative review of the empirical literature on the effect of improved medication adherence on healthcare expenditures could not draw strong conclusions about whether or not improved adherence would result in net cost savings.[35]

In summary, the extent to which VBI can reduce healthcare expenditures depends on:

- the underlying clinical risks of the population treated;
- the relative importance of cost sharing for patient adherence to high-value treatments;
- the effectiveness of those high-value services in reducing the risks, and
- the cost of the healthcare services avoided through better adherence.

6.1.3. Impact on access to healthcare

VBI reduces access to less valuable healthcare services for low-income people, while high-income patients will maintain access to drugs of marginal benefit.[28] This situation is actually not any different from the current situation where high-income people also have access to several unconventional treatments or treatments for which the evidence is limited or non-existing, while low-income people have not.[28] Some types of VBI are likely to harm people less than others. For example, a VBI by condition severity will give all people under a certain level of health status (e.g. "normal functioning") access to the lowest level of cost sharing. Access is better guaranteed in such a system than in a purely price-based or condition-based cost-sharing system. In a price-based system, high-cost treatments might be the most effective treatments but also the most costly for patients, especially in case of coinsurance. In condition severity-based VBI systems not considering the effectiveness of the standard treatment,

low-value services with marginal benefits for severe diseases with good standard treatments might be more accessible than high-value services with important benefits for somewhat less severe diseases without good standard treatment.

Price responsiveness of the demand for healthcare is a key factor when defining the level of cost sharing in a VBI design. Especially in the case of VBI by participation in a DMP, the price elasticity of the demand of the individual services included in the DMP might be of crucial importance for the eventual effectiveness of the programme.

The impact of VBI on healthcare expenditures depends on the underlying clinical risk of the population treated, the relative importance of cost sharing for patient adherence, the effectiveness of high-value services in reducing health risks and the costs of healthcare services avoided through better adherence. Therefore, VBI will not necessarily lead to savings; especially in the short run expenditures may increase due to VBI. In the long run, it is more likely that VBI induces savings.

VBI should improve access to high-value healthcare services and reduce access to low-value healthcare services, which should in principle reduce health inequalities. The better the targeting of patients, the larger the expected effect.

6.2. Real-life experiences in the US

In the US natural experiments with VBI have been performed in different employer-subsidized insurance plans. Although this system does not resemble the Belgian system, we examined whether there were lessons to learn from the practical experiences in the US. More specifically, we examined to what extent different VBI designs induce differences in outcomes in terms of health, public expenditures and total patient cost sharing.

6.2.1. Value-based co-payment tiers for pharmaceuticals

In 2007-2008, Choudhry et al. (2010) examined how the principles of VBI could be introduced in the co-payment tiers applied at the University of Michigan in the US. In a three tiered formulary, tier 1 (generics) requires the lowest patient share, tier 2 (preferred brand name) a somewhat higher patient share and tier 3 (non-preferred brand) the highest patient share. Tier systems are currently purely price-based and not clinical or economic value-based.[41] All products are classified in one of the tiers, irrespective of their indication.

Introducing a *VBI design by condition* in such a tier system, would imply the introduction of variations in patient share for drugs within the same tier. For example, the University of Michigan reduced patient cost sharing for drugs treating diabetes, high blood pressure, high cholesterol and depression by 100% for generics, 50% for tier 2 drugs and 25% for tier 3 drugs, while the patient share for the other drugs in these tiers remained unchanged (see Table 5).[10] Adherence to these drugs increased significantly after this measure. Alternatively, a *value-based by disease severity* tier system could involve no patient share for life-saving drugs, a low patient share for productivity-enhancing drugs, a moderate patient share for life-prolonging drugs and a high patient share for life-enhancing drugs.[41]

Table 5 – University of Michigan's value-based patient share tiers

	Tier 1 (generics)	Tier 2 (preferred brand)	Tier 3 (non-preferred brand)
Diabetes, high blood pressure, high cholesterol and depression drugs	$0	$7	$21
Other drugs	$7	$14	$28

6.2.2. Costs and outcomes of value-based insurance designs

The literature on the impact of VBI on health outcomes and costs is limited. The few studies that have been published each have important limitations. Not all experiments have been documented in the literature. We present a non-exhaustive list of experiments found in the literature included in Medline (PubMed) as of June 2011 in Table 6. The objective is not to provide a full systematic literature review, but rather to highlight some interesting findings from various value-based designs.

Table 6 – Summary of the empirical evidence related to VBI

Study, country (year)	Study design	VBI design	VBI intervention	Results
Pitney Bowes, US (2002)[42]	Natural experiment, non-matched control group (beneficiaries commercially insured with same pharmacy benefit manager as beneficiaries in experimental group)	VBI by condition: diabetes and vascular disease	• Elimination of patient share for statins and clopidogrel for patients with diabetes or vascular disease • Voluntary DMP for patients enrolled in the experimental group (effect not measured)	• Immediate modest increase in adherence to statins and clopidogrel in the intervention group compared to controls, but no subsequent change in monthly adherence slope. After 2 to 3 years:[29] • 26% reduction in emergency department visits post-VBI compared to pre-VBI • 7% reduction in pharmacy costs • Slower growth rate of overall healthcare expenditures
Asheville, US (2005)[6,10]	Natural experiment, no control group	VBI by condition: diabetes	• Patient share for diabetes-specific drugs and supplies for diabetic employees waived for period of 5 years • Pharmacy-led + coached self-management	• Better glucose control, compared to situation before VBI • Median healthcare spending increased • Mean healthcare spending decreased (not statistically significant) • Asthma patients: emergency room visits decreased from 9.9% to 1.3%; hospitalizations from 4.0% to 1.9% per year • Direct cost savings averaged US$ 725 per patient per year. The number of non-productive days decreased from 10.8 to 2.6 days per year
University of Michigan, US (2005)[24,29,43]	Quasi-experimental, pre-post study design with control group, drawn from other	VBI by condition: diabetes	• Patient share waived for generic diabetes medications, medications to treat or decrease diabetic complications or co-	• Statistically significant increase in adherence to diabetes drugs (+5.79%), beta-blockers (+4.43%), ACE inhibitors (+3.79%) and statins (+6.28%)[43]

Study, country (year)	Study design	VBI design	VBI intervention	Results
	employers than the University of Michigan and enrolled in the same managed care organization Break-even analysis for the VBI intervention (simulation, as uncertainty surrounding estimates of the impact of VBI on aggregate spending precluded econometric analysis)		morbidities (e.g. hypertension, dyslipidemia and depression) and non-drug-based services (e.g. yearly eye and foot examinations) • Tier two and tier three drugs' patient share reduced by 50% • Enrolment of patients in DMP • Provision of educational material to improve health and reduce risk of complications	• Intervention would break even (costs=savings) from a healthcare payer's perspective (employer+employee) if increased adherence to drug regimens would reduce non-drug medical spending by 17%. Other determinants for breaking even are the costs of non-medical interventions avoided by increased adherence. Results suggest that the Michigan intervention broke even from a healthcare payer's perspective[24] • Higher monthly medication adherence in intervention group than in control group[43] (result disputed in literature[44])
Thomas Reuters, US (2006)[45]	Natural experiment 4 groups: 1. patients with VBI + DMP (n=1 876) 2. patients with VBI + no DMP (n=328) 3. patients without VBI + DMP 4. patients without both VBI and DMP	VBI by condition	• VBI + DMP for diabetes • Lowering the coinsurance for all diabetes medications to 10%, (standard three-tiered system: coinsurance between 10% (generics) to 35% (non-preferred brands)	• Significant increase in adherence to prescription oral and insulin drugs and medical services recommended in the guidelines for patients participating in the DMP • Expenditures for all-cause prescription drugs increased after implementation of VBI, but overall expenditures remained unchanged because medical expenditures decreased • Diabetic medication adherence (medication possession ratios) was higher in patients enrolled in the VBI + DMP, as compared to patients following the DMP only
Braithwaite et al., US (2003)[23]	Computer simulation model, taking changes in demand due to changes in cost sharing	VBI by cost-effectiveness ratio (ICER) • scenario 1:	Three levels of value were: • High value: ≤ 100 000 $/LYG: decrease compared to current	• Gain in life expectancy from healthcare under prevailing cost-sharing arrangements estimated at 4.7 years.

Study, (year)	country	Study design	VBI design	VBI intervention	Results
		into account	drugs only • scenario 2: drugs + other healthcare services	cost-sharing level • Intermediate value: between 100 000 $/LYG and 300 000 $/LYG or ICER could not be estimated: no change compared to current level • Low value: > 300 000 $/LYG: increase compared to current level Calculations for budget neutral versus not budget neutral modifications in cost sharing Budget neutrality: decreases in cost sharing for high-value services not offset by increases in cost sharing for intermediate or low-value services No budget neutrality: decreases in cost sharing for high-value services offset by increases in cost sharing for intermediate or low-value services; strategy without expansion of insurance package and strategy with expansion of insurance package	Scenario 1: • Not budget neutral strategy: 0.03 LYG compared to current situation • Budget neutral strategies: between 0.03 and 0.05 additional LYG compared to current situation (i.e. 11 to 18 days), depending on how budget neutrality is obtained. Scenario 2: • Not budget neutral strategy: 0.26 LYG compared to current situation • Budget neutral strategies: between 0.24 and 0.44 additional LYG compared to current situation, depending on how budget neutrality is obtained • Overall healthcare expenditures estimated to increase by $72 per capita if budget neutrality is not imposed, because the increase in high-value service utilization not offset by a decrease in low-value service utilization

In Oregon, an ongoing natural experiment consists of increased cost sharing for overused or so-called "preference-sensitive" services.[33] Preference sensitive services are services that involve significant trade-offs for patients that may affect their decision, for example the choice between surgery or conservative treatment for low back pain. The VBI system involves the addition of two tiers compared to the current system: a "value" or "incentive" tier, consisting of services for which cost sharing is low, and a tier for preference-sensitive services, for which cost sharing is high. The value tier includes, amongst others, office visits and drugs for patients with cardiac conditions, hypertension, diabetes, and asthma. Also weight management benefits are included in this tier. The tier for preference-based services includes a.o. spinal surgery, knee and shoulder arthroscopy, hip and knee replacement, upper endoscopy, advanced imaging and sleep studies. The evaluation of this VBI is still ongoing.

All studies are natural experiments, with major limitations. Even the University of Michigan's quasi experimental pre-post study[43] has been criticized for its lack of methodological rigor.[44, 46] First, the study was based on important assumptions (e.g. about the costs of non-drug interventions avoided by increased adherence). Second, -a critique applying to all studies listed- there is largely insufficient evidence to conclude the beneficial effect of VBI on both adherence and health outcomes. Although there is some *observational* evidence that VBI is associated with increased healthcare use (e.g. Wagner et al.[10,34]), this should not be confused with a causal relationship.[44,46]

Some prudent conclusions could be drawn from the experiences with VBI in the US, in combination with our earlier analysis of the different types of VBI:

- **VBI in combination with disease management programmes seems to be superior to other VBI designs for ensuring medication adherence and adherence to recommended medical service guidelines.**
- **It is yet unclear whether VBI will improve health outcomes and reduce overall healthcare costs. There is some evidence that reduced cost sharing for high-value services will increase their use, but the relationship between increased use and health outcomes is not firmly confirmed. Increased use might also be inappropriate, in which case the relationship with better outcomes might be absent or, in the case of harms, even negative.**
- **It is yet unclear whether VBI will lead to reductions in overall healthcare expenditures in the long run. If VBI should be cost neutral for payers, patients and society in the short run, cost sharing for low-value services should increase to offset the decrease in cost sharing for high-value services.**

6.3. Evaluation of value-based insurance designs in Belgium

The evaluation of VBI designs would require an assessment of the impact on the expenditures of the RIZIV – INAMI and patients, including the effects on specific social protection mechanisms such as the maximum billing, distributional consequences of the design (e.g. are the more vulnerable socioeconomic groups more affected by the modifications in the cost sharing than the less vulnerable groups) and impact on treatment adherence through proxies such as medication possession ratio. Ideally, also the impact on health should be assessed, although this will be more difficult because of confounding. To evaluate the effectiveness of any type of VBI design in terms of clinically relevant endpoints such as mortality, a sufficiently long observation period and a rigorous study design are necessary. Instead, VBI designs are typically evaluated using observational study designs that are susceptible to bias and confounding due to unobserved health or behavioural factors threatening the validity of study findings. Ideally, a case-control design is implemented.

When an effort is made to include diagnostic information of ambulatory patients in the administrative databases, much more in-depth analyses are possible, not only related to adherence, but also related to uptake and net costs or savings of the VBI design.

Some methodological issues may be encountered in the evaluation process of a VBI by DMP. A first issue is the value-based design of the DMP. Is there sufficient evidence supporting the value of the different interventions integrated in the DMP? A related and subsequent issue concerns the evaluation of the effectiveness of the DMP. The design and implementation of the Belgian care trajectories, for instance, were preceded by two scientific projects which evaluated various interventions to improve adherence to evidence-based guidelines for diabetes.[8,47] In one of the projects, the Diabetes Leuven Project, a two-arm cluster randomized controlled trial was conducted (with before/after measurements and two intervention arms). The project demonstrated that introducing a standard package of support measures (including evidence-based treatment protocol, feedback, coaching by a specialist and a team of healthcare workers consisting of a GP, specialist, educator and dietician) significantly improved the quality of care. The Belgian Scientific Institute for Public Health (WIV – ISP) is currently collecting data on diabetes patients enrolled in the care trajectories (BMI, blood pressure, HbA1c and LDL-cholesterol). Unfortunately, no results for these parameters are available yet. For the care trajectories, no case-control design was developed.

A second issue concerns the evaluation of the value-based insurance design as part of the DMP. The main purpose of the integration of financial incentives into the design of a DMP is to encourage treatment regimes which are expected to yield clinical benefits. The success of VBI with participation in a DMP depends on the magnitude of the behavioural responsiveness to the reduction or exemption of cost sharing (the price elasticity) and the relationship between the treatment regimen and health outcomes. In addition to the question of the effectiveness of VBI, also its cost-effectiveness should be evaluated. In the short-term, VBI leads to increased costs for the public payer because of increased reimbursement of consultations and self-management education materials and lump sum payments for the coordinating GP and diabetes specialist. In the long term, the net total cost of a VBI-program depends on whether (better) health outcomes will lead to reduction in adverse events, such as hospitalizations. For the care trajectories, no RCT or other design with an intervention and comparison group for the evaluation of the cost-effectiveness were set up.

7. ILLUSTRATION OF A POSSIBLE APPLICATION OF VALUE-BASED INSURANCE PRINCIPLES TO ANTIDEPRESSANTS

7.1. Objective and scope

Antidepressants are indicated for the treatment of severe depression, panic and anxiety disorder and obsessive compulsive disorder. According to the clinical practice guidelines, long-term use (at least 6 months if and after sufficient response is seen), in combination with high-intensity psychological intervention, is required for optimal benefit.[48] Analysis of administrative data has shown, however, that in 2008 in Belgium 55% of the first treatment episodes with antidepressants consisted of only one package.[49] A point prevalence of mild depression (1.4%), moderate depression (1.1%) and severe depression (2.8%) has been reported for Belgium.[50] Evidence from Belgium and abroad show that antidepressants are in practice often used for other indications besides depression, anxiety and panic disorder; some of this use being off-label use[51-54], other supported by RCTs[55].

The disadvantage of the current administrative databases on healthcare expenditures in Belgium is, however, that they do not contain diagnostic information for ambulatory patients. It is therefore impossible to recover the reason for the prescription of antidepressants from these databases. On the other hand, duration of use can be estimated (though with important limitations) based on administrative data, assuming that patients to whom a package of drugs is delivered also take all doses included in the package at a uniform defined daily dose (DDD) regimen and at 100% adherence. This may be an overestimation of the actual use, as patients not necessarily take the drugs they buy.

Antidepressants is an interesting case for illustrating the possible financial impact of applying VBI since there seems to be an important prevalence of short-term use of antidepressants in Belgium and treatment duration can be identified from the administrative databases. We recognize that there are also arguments against the application of VBI to antidepressants in particular. We briefly discuss some of them in paragraph 7.7.1. However, we would like to emphasize that the objective of this exercise is not to make statements about how antidepressants should be reimbursed, but rather to illustrate how some weaknesses of current reimbursement could be overcome by VBI, *if* there is public support for it. Given the high proportion of single package treatments in Belgium, it should be recognized that also the current cost-sharing arrangements for these drugs might not be optimal. We only examine one particular type of VBI for antidepressants. Obviously, other designs, such as VBI by participation in a disease management programme, are possible but require the development of a DMP for depression (including non-pharmaceutical interventions) and an explicit position about the relative value of using antidepressants for treating the other indications.

The limitations of the administrative data we used (e.g. no diagnostic information for ambulatory patients, no certainty about the reasons for non-persistence to treatment), force us to make assumptions that in real life would have to be sorted out before VBI is actually implemented for antidepressants. Because the current illustration is only an exploratory exercise, we did not perform an in-depth analysis of the clinical evidence with respect to treatments with antidepressants, nor did we examine the reasons for the current patterns of use of antidepressants in Belgium. The actual implementation of a VBI design for antidepressants would require such an in-depth analysis, as well as a stronger basis for the relative value of the application of antidepressants in different indications and an assessment of the potential behavioural effects of changing cost sharing for these drugs. Antidepressants are currently reimbursed in a VBI by product design, meaning that the level of cost sharing is the same for all indications for which antidepressants are used. Antidepressants are reimbursed in category B, implying a coinsurance level of approximately 25% or 15% of the public price in 2012, depending on the eligibility of the patient for preferential reimbursement. We simulate a VBI design where

the level of reimbursement increases with the duration of treatment, the implicit assumption being that antidepressants are more valuable if they are used for indications requiring long-term treatment than if they are used for indications requiring short-term treatment. As we cannot reconstruct the process which led to the decision to put antidepressants in category B, we do not know which criteria were decisive for this decision: the severity of the main indication for antidepressants (i.e. major depression, panic, anxiety and obsessive compulsive disorder) or a weighted severity of all indications. We made the assumption that the major reason for granting reimbursement to antidepressants was their effectiveness in the treatment of major depression. Our approach could be considered as a VBI design by indication, where treatment duration is a proxy for indication. Hence, the simulated design could be called "VBI by treatment duration".

Our primary and sole objective with this example is to illustrate how one particular VBI design *could* be implemented and what the budgetary consequences would be for both patients and the RIZIV – INAMI, making abstraction of behavioural effects. Impact on patient outcomes is not examined. The exercise thus has a very restricted scope. It can be criticized and evoke objections. The actual acceptability of such an insurance design is to be judged by the decision makers, taking societal values and preferences into account.

7.2. Indications for antidepressants

7.2.1. Severe depression

Starting in the 1960s tricyclic antidepressants (TCAs, named for their chemical structure, e.g., amitriptyline, dosulepin, trazodone, imipramine, nortriptyline) came on the market to treat major depression. More recently developed antidepressants include selective monoamine oxidase inhibitors (MAOIs, mainly used in specialist care), serotonin reuptake inhibitors (SSRIs, e.g., fluoxetine, paroxetine, sertraline, citaprolam, escitaprolam) and atypical antidepressants (including mirtazapine, venlafaxine, duloxetine).

7.2.2. Label extensions

A non-exhaustive list of approved label extensions is given below:

- Fluoxetine: obsessive compulsive disorder and eating disorders (boulimia nervosa)
- Paroxetine: obsessive compulsive disorder, panic and anxiety disorders and posttraumatic stress
- Venlafaxine: panic and anxiety disorders
- Citalopram: panic disorder
- Wellbutrin (bupropion): depression
- Zyban (also bupropion): only for smoking cessation
- Tofranil (imipramine): enuresis nocturna
- Redomex (amitriptyline): neuropathic and cancer associated chronic pain
- Cymbalta (duloxetine): diabetic neuropathic pain

7.2.3. Off-label use

Off-label use includes the above-mentioned label extensions for molecules that do not have the particular indication in the label, for example, imipramine for panic and anxiety disorders and posttraumatic stress; venlafaxine, nortriptyline, fluoxetine, paroxetine for neuropathic pain;[51] citalopram for compulsive disorder; nortriptyline for smoking cessation. Meta-analyses of placebo-controlled trials have found that selective serotonin reuptake inhibitors (SSRIs; fluoxetine, paroxetine, citalopram, sertraline) or serotonin and noradrenaline reuptake inhibitors (SNRIs-selective serotonin and noradrenalin reuptake inhibitors; venlafaxine) are effective in reducing mood and physical symptoms when used continuously or 14 days before menses (usually at a lower dose than that recommended to treat a mood disorder).[52,53]

Other off-label use includes duloxetine for stress incontinence in women; amytriptiline for migraine and non-migraine headache; paroxetine for tinnitus and premature ejaculation; bupropion for ADHD in adults; sertraline and fluoxetine for obesity; mirtazapine for eating and sleeping disorders; antidepressants for irritable bowel syndrome, fibromyalgia, night sedation, agitation in dementia, gambling addiction, etc. Some off-label use has been reported as not acceptable, while some is considered acceptable depending on the source.[56] Some off-label use might even be stimulated by practice guidelines. For example, the NICE 2008 practice guideline for irritable bowel syndrome (IBS) states:[54] "The Guideline Development Group clinicians believe that at low doses (5-10 mg equivalent of amitriptyline), TCAs could be the treatment of choice for IBS, but there is a lack of evidence to support this. A newer type of antidepressant, SNRIs, may also be useful in the treatment of IBS-associated pain."

7.3. Use of antidepressants

7.3.1. Volume increase

The overall volume of antidepressant prescribing (in terms of DDDs) has increased very significantly over the past decade(s) leading to concerns of overuse. In Belgium, antidepressant use (DDDs) in ambulatory care more than doubled between 1997 and 2008.[50] An average annual increase of 6.2% has been observed between 2002 and 2010. GP prescription data from the UK show an increase in the percentage of the population that was prescribed an antidepressant: 8.0% in 1996, 11.9% in 2001, 13.4% in 2007.[57]

The increased use has led to investigations with regard to the appropriateness of initiating and continuing antidepressants. The frequency of diagnosis of depression and first prescriptions of antidepressants by GPs did not increase from 1994 to 2007 in the Intego network in Flanders.[58] This is in line with the absence of an increase in prevalence of psychiatric disorders over this period.[50] The volume increase could be the result of the use of SSRIs for more than one year,[59] in line with the recommendations in case of recurrent episodes. Alternatively or in addition, an increase in the volume of use could be explained by its use for other indications, be it on-label or off-label indications. A recent longitudinal study by the *Mutualités Socialistes/Socialistische Mutualiteiten* on the use of antidepressants in their membership, showed that the volume increase is reflected by an increase in the average number of DDDs prescribed per patient rather than by an increase in the number of patients receiving antidepressants.[49] When excluding the 55% single package prescriptions, it is observed that the median duration of the first treatment episode has increased between 2004 and 2008, from 168 days to 201 days.[49]

In addition, studies stimulate off-label use by showing the potential of immunomodulatory, analgesic and anti-inflammatory properties in antidepressants. The volume of use by indication is not well documented as most studies are based on administrative databases of drug prescriptions filled. Yet, it has been suggested that for example low-dose amitriptyline is currently predominately used for indications different from depression.[57] For amitriptyline and nortriptyline is has been reported that 81% and 65% respectively of the use is off-label. Most but not all of this off-label use is supported by evidence.[56]

7.3.2. Antidepressant treatment duration and non-persistence

Starting an antidepressant may require 4 to 8 weeks before a sufficient response is seen to a first SSRI. Side-effects may appear before, at a time there is no response yet, leading to a switch of antidepressant or to a justified treatment discontinuation. Patients who experienced side-effects with initial antidepressant treatment were likely to report similar adverse events after switching to an alternative antidepressant, even when this subsequent treatment was from a different class of antidepressants.[60]

It is also unclear what the best strategy is in case of inadequate response after 6 to 8 weeks.[48] This is the case in over 30% to 40% of the patients.[50]

Data from two general practices in Aberdeen show 29% of patients starting an antidepressant for a depressive episode received antidepressants for 60 days or less and 50% for 180 days or less.[61] An economic study from Quebec in elderly (65+) found non-persistent use (under 180 days) ranging from 50% for paroxetine to 65% for trazodone.[62] Data from a US managed care population found higher persistence rates at 30 and 180 days after 2006 compared with data obtained before, especially in elderly.[63] Non-

persistence rates were 25% to 35% after 30 days and 55% to 70% after 180 days, depending on age and time period. Psychotherapy was rarely used.

In Belgium, single prescriptions (under 30 DDDs) are observed in 27%[64] to more than 50%[49,65] of episodes of antidepressant prescriptions. It is not possible to define from the administrative data which proportion is due to justified non-persistence. Therefore, we could not take non-persistence for justified reasons into account in our analyses. We did, though, consider subsequent treatments with different products as one treatment episode.

7.4. Simulation of a value-based insurance design for antidepressants

7.4.1. Microsimulation as a tool for the analysis of policy measures

In KCE report 80[2] a microsimulation technique was used to calculate the impact of the system of maximum billing on the financial accessibility of healthcare. We refer to this report for further details on how a microsimulation model works. Simulation results give an ex ante evaluation of a policy measure, controlling for confounding factors. On the contrary, ex post evaluations, comparing the situation before and after a policy change, do not allow to control for changes that occur concurrently.

A second advantage of a microsimulation approach is that it is possible to evaluate the distributional effects of a policy change since it takes micro level units (e.g. individuals, households, firms) as the basic units of analysis. An analysis at the macro level does not give (much) information on the distributional effects of a policy since the unit of analysis is at the very best the level of specific “types” of agents.

In this report, static microsimulation modelling is applied since own-price or cross-price elasticities are not available. Hence, possible behavioural changes after a policy intervention could not be taken into account.

Data analyses and graphs were produced with SAS 9.1.3[66], and R 2.15[67] with the add-on package “lattice”.

7.4.2. Description of the data

All reimbursement data in the subsequent analysis are drawn from the EPS. The EPS[g] release 6 (EPS_{R6}) is a sample of all data available within the Belgian sickness funds as far as they are related to the compulsory insurance for healthcare. The sample size is 1 in 40 of the total Belgian population added with 1 in 20 of the Belgian population aged 65 and older. As the oversampling of people ≥65 years of age was not included in the database we used for the analysis, extrapolation of the data to the entire population hence involves multiplication of the results by 40. By doing so, we assume that the use of antidepressants in the EPS is representative for the use of antidepressants in the entire population.

This database is created and maintained by the IMA – AIM[h] and is accessible to a limited number of Belgian government agencies: RIZIV – INAMI, Federal Public Service (FPS) Public Health, WIV – ISP (Scientific Institute for Public Health), FPS Social Security, KCE, and the Federal Planning Bureau. All data are available at the level of individual reimbursements, from 2002 until 2010.

Particularly relevant to this study, the data contains per patient the following information (among others):

- The number of packages reimbursed by the compulsory health insurance (RIZIV – INAMI) per drug package (CNK code);
- The amount reimbursed to the patient by the compulsory health insurance (RIZIV – INAMI);
- The amount of patient cost sharing;
- The date of the reimbursement;
- Sociodemographic information on the patient: year of birth, gender, year and month of decease if the patient died;
- Information on the insurance entitlements of the patient.

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g http://www.riziv.be/information/nl/sampling/index.htm (Dutch); http://www.riziv.be/information/fr/sampling/index.htm (French).

h Intermutualistisch Agentschap – Agence Intermutualiste (http://www.cin-aim.be)

7.4.3. Analysis sample

From the EPS_{R6}, all patients with at least one reimbursement for one of the antidepressant drugs in ATC level 3 N06A (antidepressants) were retained. For these patients, all reimbursements for antidepressants dispensed by public pharmacies as well as by hospital pharmacies between 2002 and 2009 were taken into account. The EPS_{R6} data in their most detailed form contain corrections to previous recorded information. For analysis, corrections were taken into account as much as possible. Records with delayed deliveries[i] were excluded, as well as the detailed records of magistral preparations.[j]

Table 7 shows the delivery of antidepressants (ATC3 = N06A), total number of defined daily doses (DDD), number of packages delivered and costs for the RIZIV - INAMI and patients for the analysis sample between 2002 and 2009 (the annual delivery can be found in Appendix 1). These data are truncated: some patients started treatment before 2002, other continued after 2009.

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[i] A patient can ask a pharmacist to receive only a selection of the products on a prescription at once. If the prescribing physician did not prohibit delayed delivery on the prescription, the remaining products can be collected up to three months from the prescription date. Once collected, the registration would be counted twice if we would not exclude delayed deliveries: once for the delayed delivery, and once for the actual delivery (when the patient comes to pick it up).

[j] Pseudo-nomenclature code 750315 (French: «Préparations magistrales délivrées par les officines publiques - enregistrement de détail relatif à la préparation magistrale»; Dutch: «Magistrale bereidingen afgeleverd door publieke officina - detailrecord betreffende magistrale bereiding». There has been a change in the registration in the IMA – AIM Pharmanet database since July 2009 which has an impact on the DDDs for several molecules.

Table 7 – Total antidepressants delivery between 2002 and 2009 (sample)

ATC5	Molecule	Patients	DDD	Packages	RIZIV-INAMI costs (€)	Patients' costs (€)
N06AX11	MIRTAZAPINE	8 963	2 284 602	128 910	1 603 927.90	417 352.69
N06AX05	TRAZODONE	20 569	7 479 900	534 167	1 539 893.83	785 508.05
N06AX16	VENLAFAXINE	11 944	8 300 257	384 402	6 331 929.92	1 669 467.60
N06AX03	MIANSERIN	1 529	545 525	37 237	211 926.13	55 961.90
N06AB08	FLUVOXAMINE	900	534 720	20 504	229 789.46	94 728.97
N06AB03	FLUOXETINE	7 894	3 383 616	100 053	1 636 327.98	523 525.37
N06AB06	SERTRALINE	13 824	9 223 366	249 924	3 467 510.03	951 800.54
N06AB05	PAROXETINE	16 386	11 320 111	336 029	4 604 304.14	1 293 494.85
N06AA10	NORTRIPTYLINE	664	1 004 123	65 503	19 806.75	5 390.14
N06AX21	DULOXETINE	4 523	4 600 190	172 885	1 210 581.52	340 274.19
N06AB10	ESCITALOPRAM	19 135	11 678 912	454 085	4 382 417.29	1 230 195.65
N06AA06	TRIMIPRAMINE	34	1 957	383	767.55	208.46
N06AA01	DESIPRAMINE	32	6 100	524	1 760.25	470.02
N06AB04	CITALOPRAM	15 245	8 434 516	269 258	3 495 179.20	1 223 241.70
N06AA16	DOSULEPIN	3 199	898 023	84 674	265 314.95	73 644.79
N06AX18	REBOXETINE	1 235	247 290	13 601	239 288.85	63 262.44
N06AA04	CLOMIPRAMINE	1 471	755 249	47 177	202 268.95	52 907.21
N06AA21	MAPROTILINE	298	170 608	11 374	24 327.35	6 922.23
N06AA09	AMITRIPTYLINE	10 192	10 166 491	577 888	382 001.00	103 971.35
N06AA14	MELITRACEN	1 287	674 117	40 686	21 214.51	6 263.80
N06AA12	DOXEPIN	523	233 985	9 428	54 158.65	14 263.04
N06AX09	VILOXAZINE	120	42 138	988	15 167.63	4 290.10
N06AG02	MOCLOBEMIDE	242	107 475	3 824	65 076.79	28 493.92
N06AA02	IMIPRAMINE	501	491 321	18 946	9 027.11	2 511.23
N06AF03	PHENELZINE	19	96 125	3 845	0.00	5.10
N06AX20	HYPERICIN	<4				
Total		**70 562**	**82 687 304**	**3 566 498**	**30 013 967.74**	**8 948 155.34**
Mean per patient			**1 172**	**51**	**425.36**	**126.81**

Figure 3 and Figure 4 show the evolution of the delivery and expenditures of antidepressants over time in the selected sample. Both the number of patients and the number of DDDs have increased over time, while the total RIZIV – INAMI and patient expenditures have remained relatively stable.

Figure 3 – Evolution of expenditures for antidepressants and number of patients from 2002 to 2009 (sample)

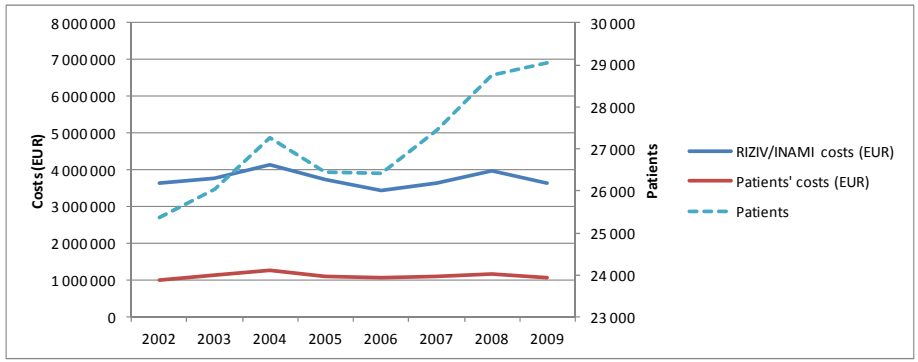


Figure 4 – Evolution of number of DDDs of antidepressants delivered from 2002 to 2009 (sample)

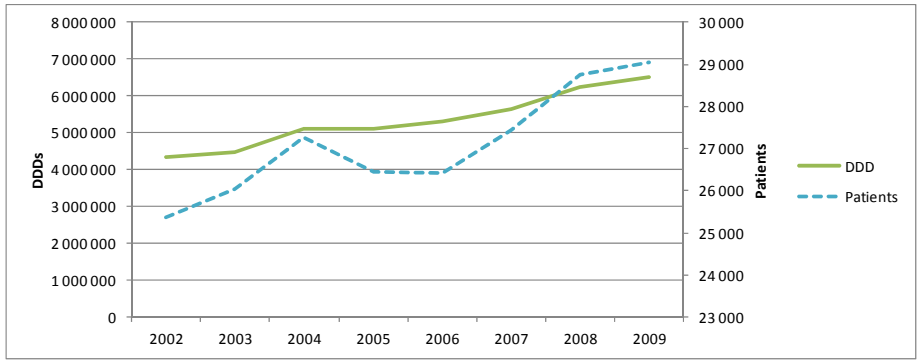


Figure based on data from Table 24 in Appendix 1.

For the microsimulations, patients who received a reimbursement for antidepressants in 2002 or whose only treatment episode continued after 31 December 2009 were excluded (n=20 733). Hence, all patients included in the sample had a first prescription of antidepressants in 2003 or later, or had a treatment-free period of at least one year. The final sample for the simulations contains 49 829 patients between 2003 and 2009.

7.4.4. Defining a treatment episode

Defining a treatment episode based on administrative data is a challenge and may lead to wrong conclusions. Different studies define a new treatment episode differently: after a gap without expected use based on defined daily doses (DDDs) received at last prescription of six months,[64] one year,[49,65] or even 4 years[68]. This has implications for the selection of patients: if a gap of four years is used to define distinct treatment episodes, patients who only take antidepressants during winter time will be considered as having a continuous treatment with antidepressants.

In this study, we define treatment episodes as starting the day of the first delivery; their end is defined as the predicted end of the last delivery, based on the total number of DDDs supplied. There are at least 6 months between 2 treatment episodes. As such, treatment-free periods can occur within one treatment episode if the time between the end of one prescription and the start of the next prescription is less than 6 months. A treatment episode can consist of different molecules, products and packages. Treatment episodes starting before 1 January 2003 have not been considered. Hence, all treatment episodes fall in the period between 1 January 2003 and 31 December 2009. Uncompleted treatments are not considered in our analyses. A treatment is defined as not completed if the date computed for the end of the treatment is after 31 December 2009.

Using the number of DDDs to define the end of a treatment episode has drawbacks. For elderly patients, this method may be inappropriate, as elderly patients on average use a lower dose compared to younger individuals, as doses are adjusted for decreasing renal and hepatic function with age. Also note that a single prescription of 250 tablets of 25 mg of amitriptyline might be sufficient to cover over a year of continued low dose (off-label) use at 5-10 mg per day. However, as we do not have

data on the actual daily dose taken by patients, using the DDD as the predicted dose per day is the best we can do.

7.4.5. Social protection measures

There are two groups of social protection mechanisms in the Belgian health insurance system. The preferential reimbursement system, reducing patient cost sharing for each encounter with the healthcare system, and the system of maximum billing (MAB) that puts an income-dependent ceiling on the total amount of cost sharing. Both measures can result in high-income patients paying more for high-value services than low-income patients are paying for low-value services.

We decided to take account of the preferential reimbursement system but not of the maximum billing in the data analysis. As will be explained in section 7.4.6, the simulation scenarios were constructed in such a way that they are on average budget neutral for patients following 6 months of pharmacological treatment. This basic assumption would not have been possible without taking account of the current characteristics of the preferential reimbursement system. The MAB, however, raises more fundamental considerations which should be made by policy makers when replacing the current VBI by product by a VBI by indication. Of course, comparable questions could/should be formulated for the preferential reimbursement system.

- Should packages for which a coinsurance level of 100% applies be excluded from the MAB, similar to non-reimbursed drugs of category D?
- Should the patient share for all treatment episodes be included in the MAB or only those for “valuable” evidence-based treatment episodes (e.g. episodes of at least 6 months for major depression)?
- Should packages for which a coinsurance level of 100% applies be excluded from the MAB *unless* they are used for valuable treatment episodes (e.g. through correction ex post)?

The actual impact on the MAB will depend on the number of patients becoming eligible for MAB reimbursements and the number of patients no longer eligible for MAB reimbursements due to the simulations. For example, if it is decided that the patient share for treatments lasting shorter than 6 months should not enter the MAB counter, a considerable number of patients might fall below the ceiling. For treatment episodes of at least 6 months -conform the clinical practice guidelines for treatment of major depression- we pursued budget neutrality for the patient. Hence, MAB reimbursements will remain unchanged for these treatment episodes if it is considered that all patient cost sharing for treatments of this duration (including the packages for which coinsurance is 100%) should enter the MAB counter. If the first package does not enter the MAB counter, MAB reimbursements will decrease. MAB reimbursements for treatment episodes of less than 6 months will be lower than they are currently if the patient share for such short-duration treatment episodes are not counted in the MAB system.

7.4.6. Simulation scenarios

We simulated two scenarios (Table 8). Both scenarios have in common that the patient has to pay a higher cost share for the first package of drugs (typically sufficient for four weeks of treatment) as compared to subsequent packages. From the 6th package onwards, the level of cost sharing remains unchanged as compared to the database used (about 25% for general public, 15% for patients with preferential reimbursement (PR)). Also, the relative advantage of patients with preferential reimbursement as compared to the general population is kept constant in all scenarios and is identical to the current relative advantage (i.e. patients with preferential reimbursement pay 40% less than patients without preferential reimbursement).

Currently, the amount to be paid as co-payment or coinsurance per package is capped. These ceilings are taken into account in as far as they are included in the data. They are applied to the simulated amounts of cost sharing if the level of cost sharing differs from 100%. For the amounts corresponding to a cost sharing level of 100%, it is assumed that the ceiling is not applied, as for other products that are not reimbursed. The ceilings applied are the ceilings prevailing at the time of the delivery of the packages.

Table 8 – Simulation scenarios for value-based insurance by treatment duration for antidepressants

	Coinsurance level package 1		Coinsurance level additional packages	
	General population	Preferential reimbursement	General population	Preferential reimbursement
Scenario 1	100%	60%	2^{nd} - 5^{th}: 10%	2^{nd} - 5^{th}: 6%
Scenario 2	75%	45%	2^{nd} - 3^{rd}: 15% 4^{rd} - 5^{th}: 10%	2^{nd} - 3^{rd}: 9% 4^{rd} - 5^{th}: 6%

The scenarios are constructed in such a way that they are on average budget neutral for patients following 6 months of pharmacological treatment and with at least 5 packages of drugs. It is impossible to simulate 100% budget neutrality for all patients following a personalized treatment schedule, because the prices of antidepressants vary between packages, brands and dosages and patients may not stick to one specific drug but may have to switch between drugs during their treatment. The budget neutral scenario was defined by trial and error, i.e. by applying different coinsurance rates for the 2^{nd} – 5^{th} packages. The extent to which the simulations deviate from budget neutrality for treatment episodes of 6 months is presented in Table 9. The data presented are population-level data (sample results multiplied by 40). A negative sign means that the patient share is higher in the simulated scenario than at baseline (before simulation). The table shows that scenario 1 is more budget neutral on the mean level of cost sharing, whereas scenario 2 is more cost neutral on the median level. Budget neutrality for the patient is one possible way to conceive a VBI design consisting of a redistribution of cost sharing across treatment episodes. Budget neutrality for the RIZIV – INAMI would be another useful one to consider.

In both scenarios the patient share increases drastically after the 5^{th} package. This choice was made because we wanted to keep the simulated scenario on average budget neutral for patients following 6 months of pharmacological treatment. However, as we defined coinsurance by package and not by DDD, we had to define from which package onwards we would keep the coinsurance as currently is. Taking the 6^{th} package instead of the 7^{th} or 8^{th} was inspired by the observation that the majority of the patients take either a package of 28-30 DDDs or a package of 56 DDDs. One package of 28 DDDs and 4 packages of 56 DDDs correspond to a treatment duration of 8.2 months. Another VBI scenario could have been to extent the cost-sharing reductions to all packages of a long-term treatment. We did not consider this option in the current analysis.

We did not use co-payments in our simulations, although we concluded in a previous chapter that these are more consistent with VBI principles. This was first and foremost a practical choice. Prices differ between types and packages of antidepressants. Obviously, the number of DDDs per package determines the price but also the type of antidepressant used. In the simulations, the level of cost sharing is defined as a coinsurance per package. In case of a co-payment per package, we would have to define a co-payment per package size, because a fixed co-payment per package, independent of the number of DDDs, would give an incentive to buy larger and more expensive packages. This would impose higher costs on the RIZIV – INAMI. It would then also be more difficult to define a budget neutral simulation for treatment episodes of 6 months and at least 5 packages, as patients can use different package sizes and different antidepressants during one episode. Moreover, differences in prices between types of antidepressants in combination with fixed co-payment might bias the results of the subgroup analyses, if specific subgroups would happen to use specific types of antidepressants more often than others.

Table 9 – Budget neutrality of simulation scenarios for treatment episodes of 6 months and ≥5 packages delivered

	Number of treatment episodes	Sum (€)	Mean (€)	25th Pctl (€)	Median (€)	75th Pctl (€)	Std Dev (€)
Scenario 1	612 960	-288 177	-0.47	-5.42	-2.89	1.84	9.08
Scenario 2	612 960	1 872 969	3.06	-0.03	0.01	4.45	7.96

7.5. Results of the baseline situation

We identified 49 829 patients and 72 376 completed treatment episodes in our sample (episodes for which we could identify both start and end), which corresponds to 1 993 160 individuals and 2 895 040 completed treatment episodes on the Belgian population level. Of these treatment episodes, 46.18% consisted of only one package. Delivery of several packages for one prescription is not considered as single package treatment episodes. The mean number of DDDs was about 130 (median=50). The mean treatment duration was almost 200 days (median=56 days). The discrepancy between the mean number of DDDs and the mean duration of a treatment episode can be explained by our definition of a treatment episode (at least 6 months between the end of the previous and the start of the next treatment episode, and the assumption that one DDD corresponds to one treatment day). Patients might need a dosage of less than 1 DDD per day (e.g. elderly patients), however, and one treatment episode could contain treatment-free periods (as defined by the DDD) of less than 6 months.

Table 10 shows the total, mean and median patient and RIZIV – INAMI expenditures for all treatment episodes included in our analyses at baseline with their indicators for the variability in the data distributions. The median number of prescriptions per treatment episode is 1 (mean=4.24) and the median cost is €9.10. The distributions are positively skewed (right tail) due to the large proportion of treatment episodes with a small number of prescriptions and a small proportion of episodes with a large number of prescriptions.

Table 10 – Descriptive statistics for the treatment episodes at baseline*

Variable	Sum	Mean	Q1	Median	Q3	Std Dev
Patient cost, €	82 253 566	28.41	4.77	9.10	25.95	54.33
RIZIV – INAMI costs, €	262 768 606	90.77	15.58	27.29	79.90	180.49
Number of DDDs	375 761 358	129.79	28.00	50.00	120.00	227.69
Prescriptions	12 275 280	4.24	1.00	1.00	4.00	7.33
Treatment duration	577 897 870	199.62	28.00	56.00	220.00	335.16

** Estimated national N based on EPS = 2 895 040*

Table 11 presents the prescriber of delivered antidepressants, in the first treatment episode within the timeframe of our analysis for all patients. The majority of the first prescriptions in the first treatment episode was made by a general practitioner.

Table 11 – Category of prescriber at the start of the first treatment episode for all patients

Category of prescriber	Patients	Percent
General Practitioner	1 512 240	76%
(Neuro)psychiatrist	137 720	7%
Other specialist	161 760	8%
Unknown	181 440	9%
Total	1 993 160	100%

Unknown = during hospitalization in more than 90% of the cases

Descriptive statistics for the baseline situation for different subgroups[k] are presented in Table 12. N refers to the number of treatment episodes.

[k] A detailed description of the subgroups can be found in Appendix 2.

Table 12 – Descriptive statistics for patient cost sharing at baseline for several population subgroups

	Yes				No			
Variable	N*	Mean	Median	Std Dev	N*	Mean	Median	Std Dev
Preferential reimbursement	588 240	21.60	6.33	43.54	2 306 800	30.15	9.85	56.62
Low income	116 680	19.84	6.43	40.55	2 778 360	28.77	9.10	54.80
Lump sum B or C	36 000	30.65	8.80	58.66	2 859 040	28.38	9.10	54.27
Having a chronic illness	309 560	28.30	7.95	56.13	2 585 480	28.43	9.10	54.11
Disability	57 800	27.35	8.65	53.79	2 837 240	28.43	9.10	54.34

Gender	Male				Female			
Age	N*	Mean	Median	Std Dev	N*	Mean	Median	Std Dev
0-19y	19 760	14.00	7.13	26.16	24 240	14.22	7.33	26.27
20-49y	420 600	25.71	9.10	48.50	741 520	29.52	10.20	52.73
50-64y	304 120	27.15	9.10	52.88	468 040	30.01	9.13	57.30
65-74y	129 600	25.46	9.05	54.39	214 400	26.13	9.10	49.41
74-85y	134 440	27.32	9.05	54.48	215 800	29.64	8.77	60.95
85+y	72 560	28.02	8.74	53.14	149 960	37.47	9.53	69.98

Unemployment status				
Variable	N*	Mean	Median	Std Dev
Not receiving unemployment benefits	2 490 040	28.79	9.10	54.97
Partial unemployment benefits	84 840	25.61	9.10	54.62
Full unemployment benefits	293 080	26.15	9.10	48.45
Other benefits	1 480	20.52	9.10	31.87
Pre-retirement benefits	25 600	27.78	9.10	54.43

** N = number of treatment episodes*

The figures in Table 12 show that being eligible for a lump sum B or C, having a chronic illness, having a disability or unemployment status do not have a huge impact on the patient share for antidepressants. The impact of being eligible for preferential reimbursement or having a low income is, however, more important.

It can be expected that, given the construct of the scenarios, the impact of the simulation on the patient share will be higher, the higher the proportion of treatment episodes with only one package.

Table 13 gives an overview of the proportion of single package treatment episodes for each population subgroup. These results show that the least vulnerable groups (no preferential reimbursement, no low income, no lump sum B or C, no chronic illness and no disability) have the highest proportions of single package treatment episodes. However, patients with full employment benefits have a higher proportion of single package treatment episodes than patients without unemployment benefits.

Table 13 – Proportion of single package treatment episodes in each subgroup

Category	Yes	No
Preferential reimbursement	43.03%	46.99%
Low income	44.81%	46.24%
Lump sum B or C	28.33%	46.41%
Having a chronic illness	35.19%	47.50%
Disability	37.92%	46.35%
Age / Gender	**Male**	**Female**
0-19y	54.66%	61.72%
20-49y	49.52%	46.73%
50-64y	47.35%	47.79%
65-74y	47.44%	46.59%
74-85y	42.90%	43.60%
85+y	34.18%	33.90%
Unemployment status		
Not receiving unemployment benefits		45.57%
Partial unemployment benefits		53.23%
Full unemployment benefits		49.22%
Other benefits		51.35%
Pre-retirement benefits		47.19%
Total		
All treatment episodes		46.18%

7.6. Results of the simulated scenarios

The simulated scenarios are always compared to the baseline situation presented in Table 12.

The results for the first and second scenario for all patients are presented in Table 14 and Table 15 respectively. The mean and median difference between the baseline and the simulation are higher for scenario 1 than for scenario 2. This is due to the combination of the specific coinsurance rates chosen for each package in each scenario and the high number of single package treatment episodes (in both scenarios). In the first scenario, all patients taking only one package have to pay the full cost (or 60% for patients with preferential reimbursement) of the package (no account taken of the ceiling). In the second, all these patients have to pay 75% or 45% for their first package. Even though patients pay 5% (or 3%) more for the 2nd and 3rd package in scenario 2 as compared to scenario 1, the fact that this concerns a smaller number of treatment episodes, explains the results.

The median difference in patient share is much smaller than the difference between the median patient share before and after simulation. This might seem strange, as the median number of packages per treatment episode was found to be 1 and the simulations are such that the level of coinsurance for the first package is 100% (non-PR) or 60% (PR) as compared to 25% (non-PR) or 15% (PR) in the baseline. In case of a uni-modal distribution, one would expect to see a larger median difference. We considered the distributions of the cost-sharing differences between simulation and baseline for treatment episodes consisting of one package, two packages, three packages, etc. to examine the face validity of the results. The distributions of the differences in cost sharing between simulation 1 or 2 and baseline are presented in Appendix 1.

The distribution is bi-modal for treatment episodes consisting of only one package, with one modus on a relatively small number of DDDs and hence a relatively small total cost of the product. If the total cost is small, the difference between 100% coinsurance and 25% coinsurance will be relatively small as well. This explains the level of the resulting median difference.

Table 14 – Results of the simulation of scenario 1 for all patients*

Variable	Sum	Mean	Q1	Median	Q3	Std Dev
Patient share, €	82 253 566	28.41	4.77	9.10	25.95	54.33
Patient share simulated, €	111 265 150	38.43	12.83	28.53	39.81	52.16
Difference between patient share and simulation, €	-29 011 584	-10.02	-18.50	-7.93	-2.57	11.13

** N patients=1 993 160; N treatment episodes = 2 895 040*

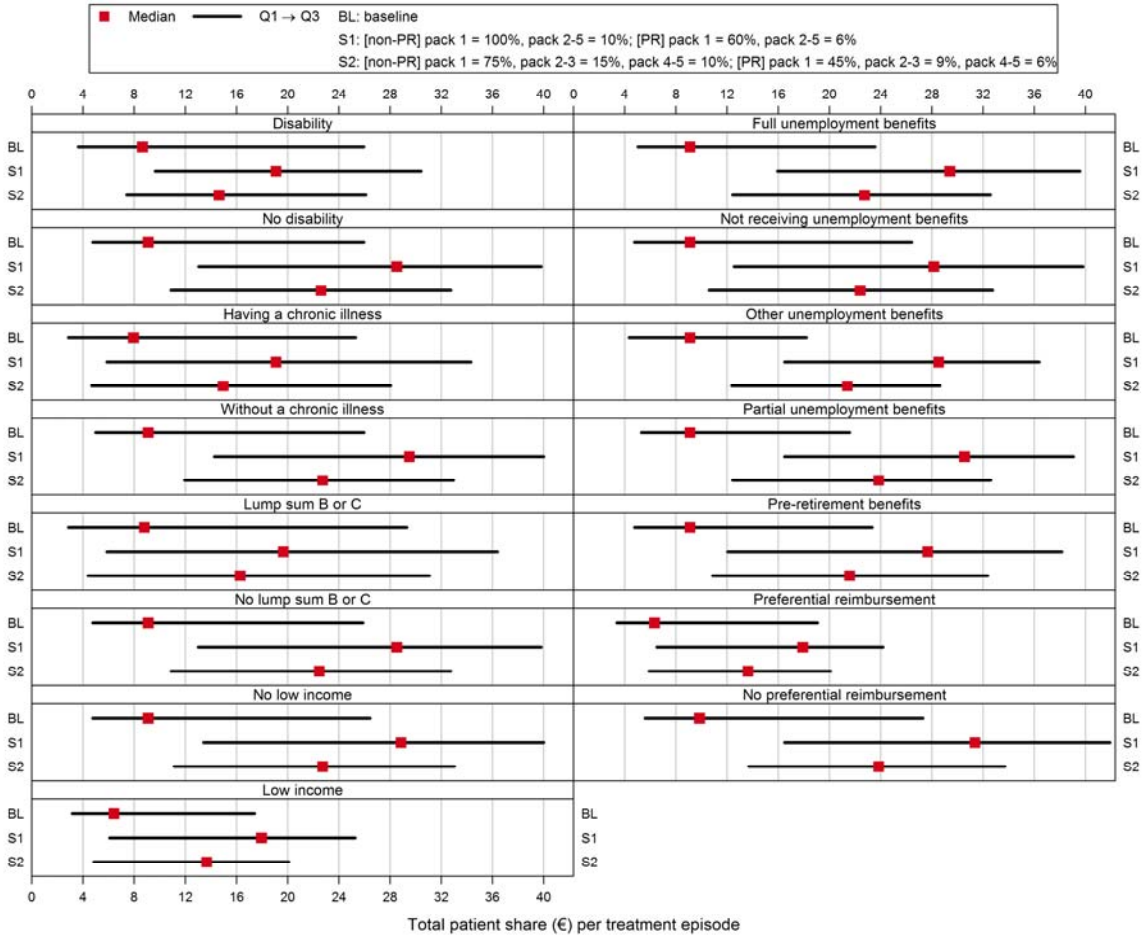
Table 15 – Results of the simulation of scenario 2 for all patients*

Variable	Sum	Mean	Q1	Median	Q3	Std Dev
Patient share, €	82 253 566	28.41	4.77	9.10	25.95	54.33
Patient share simulate, €	98 656 868	34.91	10.88	22.60	33.39	52.57
Difference between patient share and simulation, €	-16 403 302	-6.49	-12.72	-5.11	-0.08	10.29

** N patients=1 993 160; N treatment episodes = 2 895 040*

Figure 5 shows the results of the simulation of both scenarios for different subgroups, defined by socioeconomic or health status. The complete tables are presented in Appendix 4.

Figure 5 – Results of the simulation for both scenarios, by health status and socioeconomic group*



** N patients=1 993 160; N treatment episodes = 2 895 040*

The data show that the impact of the VBI design is highest for the least vulnerable groups (patients with no preferential reimbursement, no low income, no disability, no chronic illness and no lump sum B or C); these patients pay relatively more in the simulated scenarios than patients in the vulnerable groups.

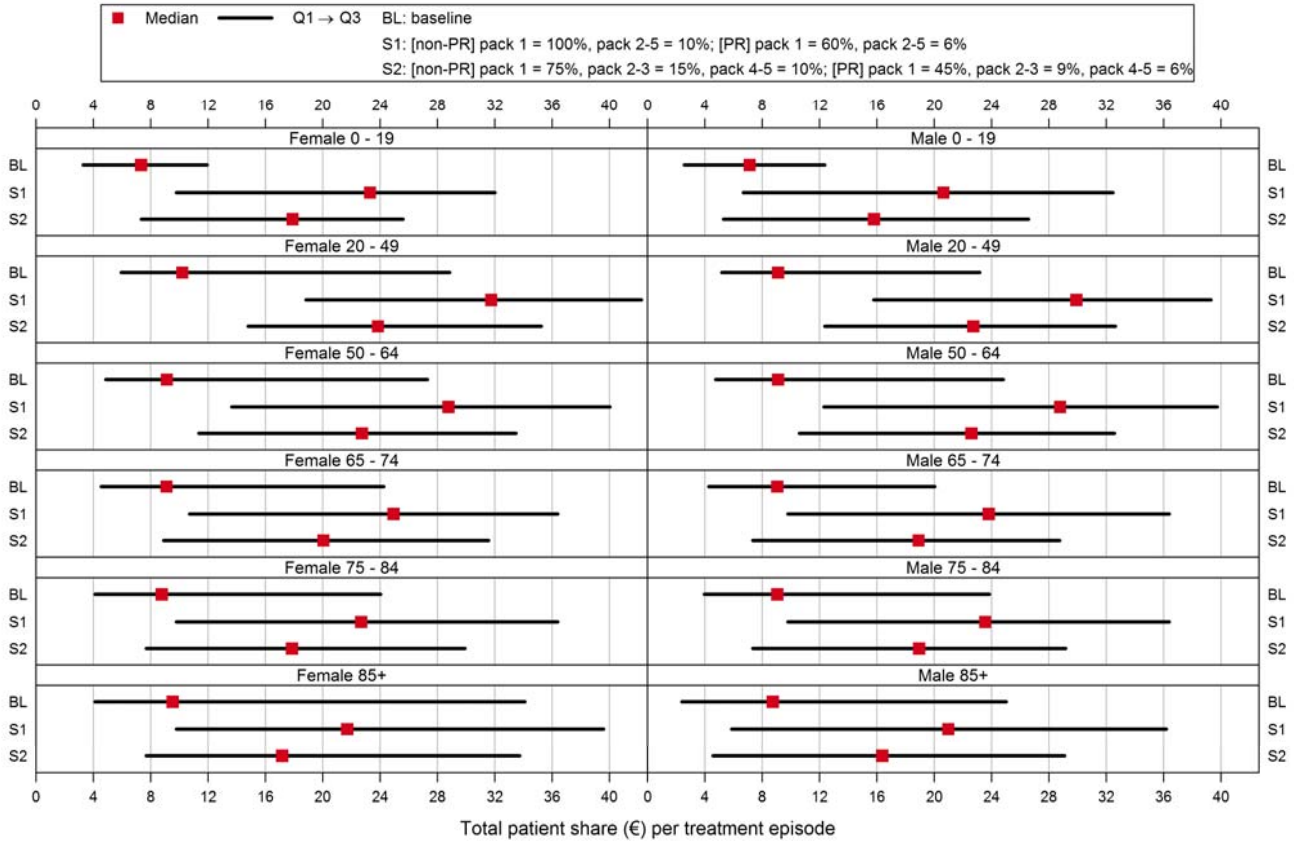
Having a low income, lump sum B or C, chronic illness or disability does not have a huge differential impact on the cost-sharing differences between simulation and baseline as compared to the data presented for patients with preferential reimbursement. For example, in scenario 1 patients with low income, entitlement to lump sum B or C, a chronic illness or disability have mean increases in their patient share for treatment with antidepressants after simulation between €4.5 and €5.5, which is similar to the patients entitled to preferential reimbursement (€4.62). The same pattern but with smaller increases in patient shares, can be observed for scenario 2.

Different results are observed for patient groups classified according to unemployment status. For patients with unemployment benefits the simulation has a bigger impact on cost sharing than for patients not entitled to unemployment benefits. This can be explained by patients with unemployment benefits having relatively more often treatment schedules consisting of one package (49.2% versus 45.6%).

The results for different subgroups defined by age and gender are presented in Figure 6. The figure shows a relatively larger increase in patient shares for the age group between 20 and 49 in both males and females, which again is a reflection of the relatively higher proportion of single package treatment episodes in this group.

For *all* subgroups, the impact of scenario 1 is bigger than the impact of scenario 2: patients pay more extra out-of-pocket in scenario 1 than in scenario 2. However, between subgroups the average impact may differ, the main driver being the proportion of patients with one-package treatment episodes (see Table 13). The policy maker will have to consider whether a reform would not disadvantage subgroups he wants to protect from too high increases in patient share. In this case, especially the stronger population subgroups are affected the most by cost-sharing modifications.

Figure 6 – Results of the simulation for both scenarios, by age and gender*



** N patients=1 993 160; N treatment episodes = 2 895 040*

7.7. Discussion

7.7.1. Appropriateness and feasibility of a higher patient cost sharing for a first prescription

In Belgium, a large number of patients that are prescribed antidepressants only take a limited number of doses. The Belgian situation is not different from the situation in some other Western countries, but seems to be in conflict with the current knowledge that, e.g. for an SSRI, it may require 4 to 8 weeks before a sufficient response is seen.

In this report, we simulated the budgetary impact for the RIZIV – INAMI and for patient subgroups of a VBI by indication design for antidepressants. The presented design is one alternative to the current insurance design for these drugs, being a level of cost sharing, regardless of the indication for which the drug is used.

Lack of diagnostic information

It was impossible with the data currently available in the administrative databases, to differentiate the level of cost sharing according to the indication. Instead, we used treatment duration as a proxy for the indication. This is obviously sub-optimal compared to a situation where diagnostic information would have been available. Using treatment duration as the basis for the VBI design implies an implicit value judgment, being that society is more inclined to pay for indications requiring a long duration treatment than for indications requiring only a short duration of treatment.

Implementation issues

Additional practical issues apply to the implementation of a VBI by indication design.

With the current healthcare system in Belgium, introducing higher patient cost sharing for a “first” prescription is not straightforward, if not impossible. Implementation of the simulated VBI design would require modifications in the current system of healthcare reimbursement. Currently, a third-party payer approach is used for prescription drugs. Patients only pay their cost share at the pharmacy. When the level of coinsurance drops for the 2nd and following boxes of drugs, either the pharmacists should be able to verify whether a patient has had a prescription before in a logical period of time, or the reimbursement should happen ex post by the sickness fund who has information on the number of prescriptions filled by individual patients. The application of the a priori approval mechanism for drugs (chapter IV) was considered not cost-effective by a group of experts.[50] The first option would require access by the pharmacist to a central database registering patients’ drug use. The second option would require patients to pay their drugs up-front, which may induce adherence problems for economically vulnerable population groups.

Another issue is the definition of a “first” prescription. There needs to be an agreement on the minimum period between prescriptions to call the new prescription a “first” prescription. The DDDs supplied at the last prescription may cover very different periods depending on the dosage used. In order to minimize possible harms, that dosage should always be the lowest possible that is still effective. Especially in elderly with many co-morbidities and co-medication, lower dosages should be the rule.

Thirdly, the question is what will be proposed for the reimbursement of antidepressants that are used for other indications, often supported by guidelines. It is an issue how this will be practically managed given that existing administrative databases do not routinely contain diagnostic information.

Fourthly, there might be a concern of wastage, potential misuse or stockpiling when a VBI design characterized by higher levels of cost sharing for first packages than for subsequent packages is implemented. This could happen if multiple packages are prescribed in one prescription.

Ethical issues

An additional concern that may be raised with respect to the application of a VBI design as described in this chapter is that patients who consult for a severe depression should not be confronted with additional obstacles to get treated. A financial barrier for the first prescription could be such an obstacle.

7.7.2. Shared responsibilities

In the application of value-based insurance principles on the use of antidepressants, the financial incentive is fully given to the patients whereas the physician decides on the prescription. Patients might not always be critical towards the prescriptions they receive. At the same time, physicians do not have to justify their prescription of antidepressants. A combination of incentives -financial or otherwise- for both patients, physicians and pharmaceutical companies might be more acceptable than targeting patients only. On the one hand, a change in mentality of patients might be needed, supported by adequate information and sensitization campaigns. On the other hand, physicians should become more aware of the clinical practice guidelines for prescription drugs and prescribe accordingly. And finally, companies could be made responsible for the effectiveness of their products through, for instance, risk-sharing schemes, to reduce strategies that aim to increase the market beyond the indications for which the treatment is considered valuable.

Limitation of prescription to specialists could be an alternative to VBI for these drugs. However, this presumes that all indications for which antidepressants could be appropriately prescribed require a consultation with a specialist.

8. CONCLUSION

VBI has the potential to improve quality and efficiency of healthcare by stimulating the use of high-value healthcare services and reducing the use of low-value services. In the short term, total expenditures might increase through an increased use of high-value services with lower cost sharing. Therefore, it is important to combine a reduction in cost sharing for high-value services with an increase in cost-sharing for low-value services.

VBI requires mechanisms to (1) define the value of a healthcare service, and (2) efficiently target cost-sharing reductions. The first condition requires explicit criteria for the determining the value of services, that are applied consistently across the healthcare sector. The second condition presumes adequate information technology and auditing of the appropriateness of information reporting.

The choice of the most appropriate VBI design for a particular service combination depends on the type of service (e.g. consultation or drug), its risk of inefficient use and the extent of such inefficient use (large versus small population), and its cost. A good balance between feasibility and effectiveness of the VBI system needs to be sought. It is unlikely that one system will fit all. Nevertheless, integration of VBI as a basic principle of the cost-sharing arrangements in the healthcare system is desirable.

Empirical evidence on the effects of VBI on healthcare outcomes and costs are still limited and coming mainly from the US. The relevance of the examples from the US for the Belgian situation is limited. Moreover, Belgium already applies VBI in pharmaceuticals and some other healthcare services.

A good example of VBI in Belgium is the elimination of cost sharing for services used in the context of a disease management programmes (end-stage renal disease and diabetes type 2). Several studies from the US have suggested that this type of VBI -called VBI by participation- is more effective in increasing patient adherence than applying VBI by condition alone or disease management alone. The number of disease management programmes is still limited as of now, but they seem to be a useful first step for implementing VBI.

VBI is most developed in Belgium in the pharmaceutical sector. Sophisticated VBI mechanisms have been developed for some products, such as statins, with close relationships between cost sharing and relative value of the product. One possible issue with the cost-sharing mechanisms in the pharmaceutical sector is the definition of the reimbursement categories, which are now mostly based on condition severity without treatment, and the use of coinsurance levels rather than co-payments. The coinsurance levels are not adapted to the relative importance of the incremental benefits offered by new treatments for which effective high-value treatments already exist. This may lead to situations where new products with marginal incremental benefits for severe conditions if not treated are fully reimbursed, while products with substantial incremental benefits for less severe conditions that are not yet well controlled with current treatment are getting increasingly expensive for patients, as prices tend to increase with value as well. This is in conflict with the principles of VBI. A possible solution is to allow products to be classified in a lower reimbursement category, although they are for severe diseases, if high-value alternative treatments exist for which the patient share would still be low. Or, alternatively, substitute the coinsurance system with a co-payment system, where co-payment categories are defined by therapeutic need and incremental value instead of medical need and absolute value. This would allow classification of products with low incremental value for low therapeutic needs into a category with higher co-payments.

VBI designs that take the effectiveness of existing treatments into account (therapeutic need) are more appropriate than VBI designs focusing only on medical need (condition severity without treatment). If no treatments are available for a specific condition, therapeutic need is high. Medical need refers to severity of the condition. The concepts of medical and therapeutic need are important because they surpass the pure economic efficiency approach based on cost-effectiveness, where priority is given to interventions contributing the most to the total health of a population, irrespective of whether they are for high or low medical needs.[17] This also implies that if medical and therapeutic need are considered to be important determinants for value, VBI cannot be purely based on cost-effectiveness.

VBI is a demand-side financial incentive for efficient use of healthcare in a context where cost sharing exists and is accepted as basic measure to reduce moral hazard and steer healthcare consumers' behaviour. The place of VBI amongst other financial incentives for efficient and high-value healthcare, such as pay-for-performance mechanisms for providers or deductibles for patients, needs to be determined. Different systems might co-exist. For example, the VBI logic could ensure full coverage of high-value services that would otherwise be taken into account for the definition of the deductible.[13,31] The alignment of clinical and financial incentives for patients and providers, will encourage the use of high-value care while discouraging the use of low-value or unproven services. Non-financial incentives to increase appropriate use of healthcare encompass the development of stimulation of participation in disease management programmes, feedback mechanisms for providers or the development of clinical practice guidelines.

At the same time pricing policies should be developed to ensure prices are value-based in order to maintain financial sustainability and acceptability of public financial responsibility for the costs of healthcare services. Possibilities include VBP negotiations, reference pricing or risk sharing agreements between the public payer and the pharmaceutical industry.

APPENDICES

APPENDIX 1. USE OF ANTIDEPRESSANTS IN BELGIUM: ANNUAL DELIVERY

All tables are based on the Permanent Sample (EPS).

Table 16 – Antidepressants delivery 2002 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA01	DESIPRAMINE	17	2 350	94	655.68	176.13
N06AA02	IMIPRAMINE	141	9 890	1 397	1 887.44	521.76
N06AA04	CLOMIPRAMINE	523	63 860	3 687	29 702.94	7 739.56
N06AA06	TRIMIPRAMINE	34	1 893	377	744.50	200.77
N06AA09	AMITRIPTYLINE	2 218	198 093	13 673	46 006.85	12 429.98
N06AA10	NORTRIPTYLINE	96	11 254	1 419	1 886.04	526.35
N06AA12	DOXEPIN	200	25 933	1 182	8 717.35	2 243.15
N06AA14	MELITRACEN	504	56 718	3 511	5 759.02	1 708.30
N06AA16	DOSULEPIN	1 192	99 002	8 881	39 887.91	10 975.31
N06AA21	MAPROTILINE	112	10 278	729	4 107.85	1 169.69
N06AB03	FLUOXETINE	3 035	522 658	20 623	308 214.42	94 522.73
N06AB04	CITALOPRAM	6 128	934 280	49 228	849 129.87	229 528.04
N06AB05	PAROXETINE	5 182	719 685	33 778	747 206.57	209 150.62
N06AB06	SERTRALINE	3 920	550 134	24 701	526 828.94	144 470.03
N06AB08	FLUVOXAMINE	421	78 300	2 833	52 070.27	17 740.94
N06AF03	PHENELZINE	4	13 550	542	0.00	0.00
N06AG02	MOCLOBEMIDE	121	24 135	1 533	20 332.17	4 442.08
N06AX03	MIANSERIN	601	66 105	4 482	39 742.67	10 248.01
N06AX05	TRAZODONE	5 336	346 020	30 930	234 747.05	62 205.50
N06AX09	VILOXAZINE	91	21 385	519	7 831.19	2 196.80
N06AX11	MIRTAZAPINE	1 443	139 470	7 446	139 322.92	37 236.40
N06AX16	VENLAFAXINE	2 965	400 533	25 426	525 096.14	134 767.91
N06AX18	REBOXETINE	444	40 560	3 588	40 633.46	10 333.30
Total		**25 367**	**4 336 083**	**240 579**	**3 630 511.25**	**994 533.36**
Mean per patient			**170.93**	**9.48**	**143.12**	**39.21**

Table 17 – Antidepressants delivery 2003 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA01	DESIPRAMINE	13	1 075	323	343.19	80.50
N06AA02	IMIPRAMINE	129	7 346	1 070	1 418.37	390.49
N06AA04	CLOMIPRAMINE	480	61 051	4 367	30 022.88	7 685.86
N06AA06	TRIMIPRAMINE	4	65	6	23.05	7.69
N06AA09	AMITRIPTYLINE	2 165	192 989	13 285	45 914.94	12 381.04
N06AA10	NORTRIPTYLINE	107	12 167	1 465	2 098.33	575.09
N06AA12	DOXEPIN	193	21 820	1 031	8 654.74	2 206.84
N06AA14	MELITRACEN	537	28 667	1 789	5 803.10	1 711.13
N06AA16	DOSULEPIN	1 055	89 186	7 585	36 963.98	10 253.26
N06AA21	MAPROTILINE	91	8 635	708	3 537.75	1 005.88
N06AB03	FLUOXETINE	2 670	442 020	16 314	259 075.14	81 559.63
N06AB04	CITALOPRAM	5 534	868 718	42 174	709 145.08	248 109.04
N06AB05	PAROXETINE	5 231	781 775	33 267	804 057.30	223 316.70
N06AB06	SERTRALINE	3 690	552 492	26 024	548 435.05	150 449.17
N06AB08	FLUVOXAMINE	338	64 320	2 486	40 739.93	17 719.13
N06AB10	ESCITALOPRAM	2 648	205 604	10 738	194 120.11	53 072.10
N06AF03	PHENELZINE	4	36 850	1 474	0.00	0.00
N06AG02	MOCLOBEMIDE	89	17 385	672	10 561.85	6 191.62
N06AX03	MIANSERIN	541	58 955	4 255	35 534.88	9 284.68
N06AX05	TRAZODONE	5 393	356 080	31 508	218 057.26	90 554.18
N06AX09	VILOXAZINE	70	19 112	426	6 858.42	1 948.07
N06AX11	MIRTAZAPINE	1 650	166 470	9 080	173 692.86	45 427.29
N06AX16	VENLAFAXINE	3 092	447 027	27 830	607 178.15	160 897.89
N06AX18	REBOXETINE	392	38 190	2 021	38 676.79	10 089.38
Total		**26 034**	**4 477 999**	**239 898**	**3 780 913.15**	**1 134 916.66**
Mean per patient			**172.01**	**9.21**	**145.23**	**43.59**

Table 18 – Antidepressants delivery 2004 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA01	DESIPRAMINE	13	2 000	80	565.72	163.16
N06AA02	IMIPRAMINE	130	7 726	1 065	1 501.68	388.17
N06AA04	CLOMIPRAMINE	450	59 002	3 646	26 977.44	7 063.79
N06AA09	AMITRIPTYLINE	2 284	209 494	12 829	47 489.66	12 771.65
N06AA10	NORTRIPTYLINE	119	13 384	1 058	2 240.95	611.78
N06AA12	DOXEPIN	191	21 485	1 077	7 842.11	2 058.33
N06AA14	MELITRACEN	603	32 417	1 957	6 218.66	1 841.71
N06AA16	DOSULEPIN	1 012	91 842	7 776	36 189.05	9 926.06
N06AA21	MAPROTILINE	91	8 763	589	3 291.52	948.98
N06AB03	FLUOXETINE	2 529	459 574	12 843	243 344.38	75 986.20
N06AB04	CITALOPRAM	4 372	743 678	33 084	496 971.73	209 475.57
N06AB05	PAROXETINE	5 015	898 299	34 370	842 004.38	232 082.99
N06AB06	SERTRALINE	3 873	613 434	27 115	594 136.49	162 534.78
N06AB08	FLUVOXAMINE	299	59 580	2 984	37 696.62	15 514.04
N06AB10	ESCITALOPRAM	4 649	591 248	31 691	549 480.95	152 008.26
N06AF03	PHENELZINE	5	18 800	752	0.00	0.00
N06AG02	MOCLOBEMIDE	69	14 260	402	8 287.85	4 444.47
N06AX03	MIANSERIN	478	55 215	3 395	31 972.08	8 403.86
N06AX05	TRAZODONE	5 672	390 110	31 762	197 658.37	112 256.91
N06AX09	VILOXAZINE	18	1 305	36	445.60	134.43
N06AX11	MIRTAZAPINE	1 846	191 316	11 398	203 975.10	53 187.26
N06AX16	VENLAFAXINE	3 473	584 472	32 737	772 449.17	189 710.26
N06AX18	REBOXETINE	359	41 160	1 498	41 438.54	10 993.79
N06AX20	HYPERICIN	<4				
Total		**27 278**	**5 110 003**	**254 204**	**4 152 178.05**	**1 262 506.45**
Mean per patient			**187.33**	**9.32**	**152.22**	**46.28**

Table 19 – Antidepressants delivery 2005 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA01	DESIPRAMINE	10	625	25	195.66	50.23
N06AA02	IMIPRAMINE	112	6 484	1 176	1 212.76	337.14
N06AA04	CLOMIPRAMINE	416	52 171	2 940	23 573.34	6 154.14
N06AA09	AMITRIPTYLINE	2 355	201 455	13 859	45 925.98	12 434.21
N06AA10	NORTRIPTYLINE	155	13 084	2 211	2 326.30	585.94
N06AA12	DOXEPIN	168	18 283	645	6 572.60	1 725.93
N06AA14	MELITRACEN	409	17 900	1 084	3 426.86	1 000.95
N06AA16	DOSULEPIN	936	81 881	6 413	32 006.06	8 893.35
N06AA21	MAPROTILINE	84	7 658	579	2 907.78	812.46
N06AB03	FLUOXETINE	2 079	403 088	11 403	194 058.59	62 618.84
N06AB04	CITALOPRAM	3 630	669 924	22 620	362 849.25	141 015.20
N06AB05	PAROXETINE	4 656	899 863	27 776	538 287.25	151 909.72
N06AB06	SERTRALINE	3 622	652 578	24 050	562 529.60	149 942.85
N06AB08	FLUVOXAMINE	231	49 080	2 260	25 793.70	11 407.13
N06AB10	ESCITALOPRAM	5 010	691 236	36 188	636 694.64	176 123.46
N06AF03	PHENELZINE	4	20 325	813	0.00	0.00
N06AG02	MOCLOBEMIDE	61	11 655	382	6 635.32	3 478.03
N06AX03	MIANSERIN	397	47 585	2 390	27 125.50	7 137.97
N06AX05	TRAZODONE	5 595	369 250	29 316	177 144.56	105 104.97
N06AX09	VILOXAZINE	<4				
N06AX11	MIRTAZAPINE	1 969	210 000	14 738	224 875.76	57 300.15
N06AX16	VENLAFAXINE	3 457	644 427	32 615	842 111.83	207 444.19
N06AX18	REBOXETINE	314	34 500	1 692	33 333.02	8 835.16
Total		**26 446**	**5 103 162**	**235 177**	**3 749 618.78**	**1 114 322.82**
Mean per patient			**192.97**	**8.89**	**141.78**	**42.14**

Table 20 – Antidepressants delivery 2006 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA02	IMIPRAMINE	96	4 500	1 118	889.79	259.88
N06AA04	CLOMIPRAMINE	424	54 866	2 804	24 469.23	6 522.16
N06AA09	AMITRIPTYLINE	2 471	207 379	14 003	46 086.45	12 769.85
N06AA10	NORTRIPTYLINE	171	15 317	1 678	2 521.38	665.90
N06AA12	DOXEPIN	132	15 683	596	5 604.40	1 477.12
N06AA16	DOSULEPIN	844	77 827	6 471	30 258.63	8 478.54
N06AA21	MAPROTILINE	78	7 850	470	2 908.69	833.60
N06AB03	FLUOXETINE	1 845	367 676	9 886	162 844.79	54 352.59
N06AB04	CITALOPRAM	3 427	641 774	19 102	294 161.73	110 857.09
N06AB05	PAROXETINE	4 411	886 305	24 083	433 687.58	123 667.99
N06AB06	SERTRALINE	3 627	740 742	20 547	341 033.98	95 626.70
N06AB08	FLUVOXAMINE	203	41 550	1 423	20 362.83	9 168.16
N06AB10	ESCITALOPRAM	5 192	757 624	39 462	688 738.75	193 265.85
N06AF03	PHENELZINE	<4				
N06AG02	MOCLOBEMIDE	50	9 975	205	5 337.43	2 819.00
N06AX03	MIANSERIN	378	43 860	2 187	22 934.07	6 164.97
N06AX05	TRAZODONE	5 645	376 370	29 098	169 361.84	101 384.49
N06AX11	MIRTAZAPINE	2 141	258 252	16 046	193 377.50	49 612.57
N06AX16	VENLAFAXINE	3 281	686 860	32 618	859 160.34	241 910.24
N06AX18	REBOXETINE	251	23 940	1 313	24 429.68	6 496.25
N06AX20	HYPERICIN	<4				
N06AX21	DULOXETINE	1 045	89 236	4 463	113 749.78	32 280.27
Total		**26 432**	**5 312 568**	**227 749**	**3 441 918.87**	**1 058 618.32**
Mean per patient			**200.99**	**8.62**	**130.22**	**40.05**

Table 21 – Antidepressants delivery 2007 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA02	IMIPRAMINE	75	3 740	870	674.49	200.16
N06AA04	CLOMIPRAMINE	385	51 505	3 298	23 048.61	6 050.09
N06AA09	AMITRIPTYLINE	2 609	210 674	14 785	47 244.69	13 009.50
N06AA10	NORTRIPTYLINE	169	15 317	1 897	2 375.41	656.41
N06AA12	DOXEPIN	137	15 303	529	5 408.31	1 458.51
N06AA16	DOSULEPIN	873	77 804	6 204	30 230.33	8 514.72
N06AA21	MAPROTILINE	66	7 165	557	2 632.38	756.02
N06AB03	FLUOXETINE	1 782	359 488	8 619	156 485.26	51 496.44
N06AB04	CITALOPRAM	3 211	627 918	17 007	270 776.02	99 864.71
N06AB05	PAROXETINE	4 257	883 961	23 265	422 267.75	121 150.35
N06AB06	SERTRALINE	3 466	777 544	19 107	302 330.71	83 988.88
N06AB08	FLUVOXAMINE	171	39 240	1 373	18 891.40	8 489.82
N06AB10	ESCITALOPRAM	5 860	876 568	44 139	743 454.21	211 436.62
N06AF03	PHENELZINE	<4				
N06AG02	MOCLOBEMIDE	46	9 765	203	5 138.41	2 636.96
N06AX03	MIANSERIN	355	40 030	2 444	19 044.16	5 141.17
N06AX05	TRAZODONE	6 024	381 400	31 738	171 850.40	99 776.81
N06AX11	MIRTAZAPINE	2 205	289 288	16 618	211 250.63	55 457.10
N06AX16	VENLAFAXINE	3 363	728 115	34 474	900 328.81	254 193.35
N06AX18	REBOXETINE	193	20 220	1 172	20 565.53	5 591.64
N06AX21	DULOXETINE	1 819	234 038	10 318	296 422.58	84 124.87
Total		**27 444**	**5 649 282**	**238 625**	**3 650 420.09**	**1 113 994.13**
Mean per patient			**206**	**9**	**133.01**	**40.59**

Table 22 – Antidepressants delivery 2008 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA02	IMIPRAMINE	82	4 230	809	767.59	216.95
N06AA04	CLOMIPRAMINE	363	51 872	3 010	22 922.00	5 992.71
N06AA09	AMITRIPTYLINE	2 812	227 968	16 296	52 213.67	14 181.82
N06AA10	NORTRIPTYLINE	168	16 700	1 128	2 577.58	724.12
N06AA12	DOXEPIN	146	16 775	523	5 847.95	1 582.19
N06AA14	MELITRACEN	<4				
N06AA16	DOSULEPIN	860	80 254	6 377	31 070.04	8 686.74
N06AA21	MAPROTILINE	70	7 365	576	2 739.87	765.16
N06AB03	FLUOXETINE	1 715	368 556	8 908	159 517.67	52 531.89
N06AB04	CITALOPRAM	3 044	623 372	14 507	264 568.89	96 065.59
N06AB05	PAROXETINE	4 175	920 536	23 760	432 630.44	123 075.72
N06AB06	SERTRALINE	3 383	824 486	19 487	308 209.16	85 769.81
N06AB08	FLUVOXAMINE	174	36 900	1 565	17 766.20	7 651.07
N06AB10	ESCITALOPRAM	6 495	1 139 936	41 490	802 388.03	227 804.93
N06AF03	PHENELZINE	<4				
N06AG02	MOCLOBEMIDE	44	8 780	191	4 401.72	2 309.53
N06AX03	MIANSERIN	359	39 620	1 968	18 879.75	5 081.99
N06AX05	TRAZODONE	6 365	410 890	30 787	184 576.23	106 778.21
N06AX11	MIRTAZAPINE	2 323	320 941	17 219	229 899.10	59 723.89
N06AX16	VENLAFAXINE	3 625	835 678	39 138	1 035 067.99	275 309.79
N06AX18	REBOXETINE	185	21 480	1 181	21 675.16	5 889.26
N06AX20	HYPERICIN	<4				
N06AX21	DULOXETINE	1 994	295 732	12 810	373 027.46	105 494.36
Total		**28 747**	**6 258 353**	**241 945**	**3 970 746.50**	**1 185 635.73**
Mean per patient			**223.07**	**8.42**	**138.13**	**41.24**

Table 23 – Antidepressants delivery 2009 (EPS)

ATC5	Molecule	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
N06AA02	IMIPRAMINE	69	3 862	717	674.99	196.68
N06AA04	CLOMIPRAMINE	368	49 945	1 948	21 552.51	5 698.90
N06AA09	AMITRIPTYLINE	2 839	230 424	14 364	51 115.01	13 993.30
N06AA10	NORTRIPTYLINE	166	16 617	1 231	3 780.76	1 044.55
N06AA12	DOXEPIN	140	16 825	587	5 511.19	1 510.97
N06AA16	DOSULEPIN	827	74 669	6 515	28 708.95	7 916.81
N06AA21	MAPROTILINE	67	6 020	456	2 201.51	630.44
N06AB03	FLUOXETINE	1 695	363 778	9 407	152 787.73	50 457.05
N06AB04	CITALOPRAM	2 869	608 756	13 255	247 558.52	88 326.46
N06AB05	PAROXETINE	3 898	878 058	21 468	384 162.87	109 140.76
N06AB06	SERTRALINE	3 423	835 756	19 169	284 006.10	79 018.32
N06AB08	FLUVOXAMINE	170	35 610	1 242	16 468.51	7 038.68
N06AB10	ESCITALOPRAM	6 621	1 216 208	38 164	767 540.60	216 484.43
N06AF03	PHENELZINE	<4				
N06AG02	MOCLOBEMIDE	46	8 975	183	4 382.04	2 172.23
N06AX03	MIANSERIN	328	37 080	2 051	16 693.02	4 499.25
N06AX05	TRAZODONE	6 546	423 230	31 229	186 498.12	107 446.98
N06AX11	MIRTAZAPINE	2 404	346 771	17 631	227 534.03	59 408.03
N06AX16	VENLAFAXINE	3 882	1 005 026	33 326	790 537.49	205 233.97
N06AX18	REBOXETINE	158	18 360	840	18 536.67	5 033.66
N06AX21	DULOXETINE	2 076	337 852	15 175	427 381.70	118 374.69
Total		**29 036**	**6 514 246**	**228 975**	**3 637 632.32**	**1 083 626.16**
Mean per patient			**224.35**	**7.89**	**125.28**	**37.32**

Table 24 – Antidepressants delivery 2002-2009 (EPS)

Year	Total					Mean			
	Patients	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)	DDD	Packages	RIZIV/INAMI costs (€)	Patients' costs (€)
2002	25 367	4 336 083	240 579	3 630 511	994 533.36	170.93	9.48	143.12	39.21
2003	26 034	4 477 999	239 898	3 780 913	1 134 916.66	172.01	9.21	145.23	43.59
2004	27 278	5 110 003	254 204	4 152 178	1 262 506.45	187.33	9.32	152.22	46.28
2005	26 446	5 103 162	235 177	3 749 619	1 114 322.82	192.97	8.89	141.78	42.14
2006	26 432	5 312 568	227 749	3 441 919	1 058 618.32	200.99	8.62	130.22	40.05
2007	27 444	5 649 282	238 625	3 650 420	1 113 994.13	205.85	8.69	133.01	40.59
2008	28 747	6 258 353	241 945	3 970 747	1 185 635.73	217.70	8.42	138.13	41.24
2009	29 036	6 514 246	228 975	3 637 632	1 083 626.16	224.35	7.89	125.28	37.32
2002-2009	70 452	42 761 696	1 907 152	30 013 939	8 948 153.63	606.96	27.07	426.02	127.01

APPENDIX 2. DEFINITION OF VARIABLES USED IN THE ANALYSIS

We used variables and flags from Population and Health services databases. The difference between a variable and a flag is that the latter results from combining different variables or regrouping different categories from one single variable. Flags were created with the purpose of providing well documented and coherent analysis tools (or variables) to the different users of the EPS. Variables and flags selected for the analysis provide information on individuals' demographic and socioeconomic characteristics, indicators of health status and on variables related to the reimbursement level of different health services.

Table 25 – Definition of variables used in the analysis

Group	Variable	Definition and category	Source	Variable/flag in database
Demographic	Gender and age	The variable age was grouped into seven categories: 0-9, 10-19, 20-49, 50-64, 65-74, 75-84 and 85+, separately for men and women.	Population	PP0015A (year of birth) and PP0020 (gender)
Health status	Disability	Dichotomous variable giving information on whether the person was recognized as disabled.	Population	Flag recognition_YN. This flag is based on the variable PP1009 "origin of the recognition of disability". If PP1009 is equal to zero, the individual is not considered as being disabled. If PP1009 is not equal to zero (categories one to seven), the individual has an official recognition of disability. Disability recognition can be given by: the Medical control service (PP1009=1)[1], the Belgian Federal Public Service Social Security (PP1009=2)[2], to handicapped children (physical or mental handicap evaluated at least at 66%[3], PP1009=3,4), to self-employed individuals receiving invalidity benefits (and to their widow/widower, PP1009=5,6,7)[4]
	Lump sum B or C	Dichotomous variable giving information on individuals who received a lump sum that compensates extra expenses accompanied by a chronic illness. Two conditions have to be fulfilled at the same time. First, the amount of co-payments exceeds a threshold of €450 for patients without preferential reimbursement and €365 for patients with preferential reimbursement during two consecutive years. A second condition concerns the degree of dependency during the current calendar year.	Population	Computed combining PP2001 (equal to one for a person receiving a lump sum B) and PP2002 (equal to one for a person receiving a lump sum C). A value of one on either of these was sufficient.
	Having a chronic illness or handicap	Dichotomous variable giving information on whether the person received a lump sum or an allowance relating to having a chronic illness or handicap during the year.	Population	Uses the flag chronical_YN. This flag combines variables PP2001 to PP2011 and PP3011. PP2001 to PP2003 provide information on different lump sums (PP2001=lump sum B, PP2002=lump sum C, PP2003=physiotherapy E). PP2004 to PP2009 provide information on allowances attributed to disabled individuals (both for disability related to old age and handicap). Allowances include increased family allowance (PP2004), integration allowance for

Group	Variable	Definition and category	Source	Variable/flag in database
				handicapped (PP2005), allowance for assistance to the elderly person (PP2006), allowance for assistance to a third person (PP2007), increased disability allowance for assistance to a third person (PP2008), lump sum allowance for assistance to a third person (PP2009) and income replacement allowance for individuals aged 21 to 65 years old (PP3003). PP2010 and 2011 provide information on long-term hospitalisation (PP2010 being hospitalized for at least 120 days and PP2011 being hospitalized at least 6 times during the reference year).
Reimbursement related variables	Preferential reimbursement	Dichotomous variable giving information whether the patient has right to increased reimbursement of patient cost sharing.	Population	Computed based on variable PP0030
Socioeconomic	Unemployment status	Five categories are included for this variable. Individuals can either receive: i) Full unemployment benefits, ii) Partial unemployment benefits, iii) Pre-retirement benefits, iv) Not considered as unemployed and v) Missing information.	Population	Uses the flag unemployment_YN. The flag is based on the variable PP1004 which contains information on codes included in the unemployment certificates. PP1004 has ninety-nine categories[5].
	Low income	Dichotomous variable indicating whether a person receives a minimum guaranteed income or assistance from a public municipal welfare centre.	Population	PP3010 and PP3013 were combined to create this variable (a large overlap between both variables exists). PP3010 is equal to one for individuals receiving an income guarantee for the elderly or a subsistence level income (zero otherwise). PP3013 is equal to one for individuals receiving support from a municipal welfare centre[6].

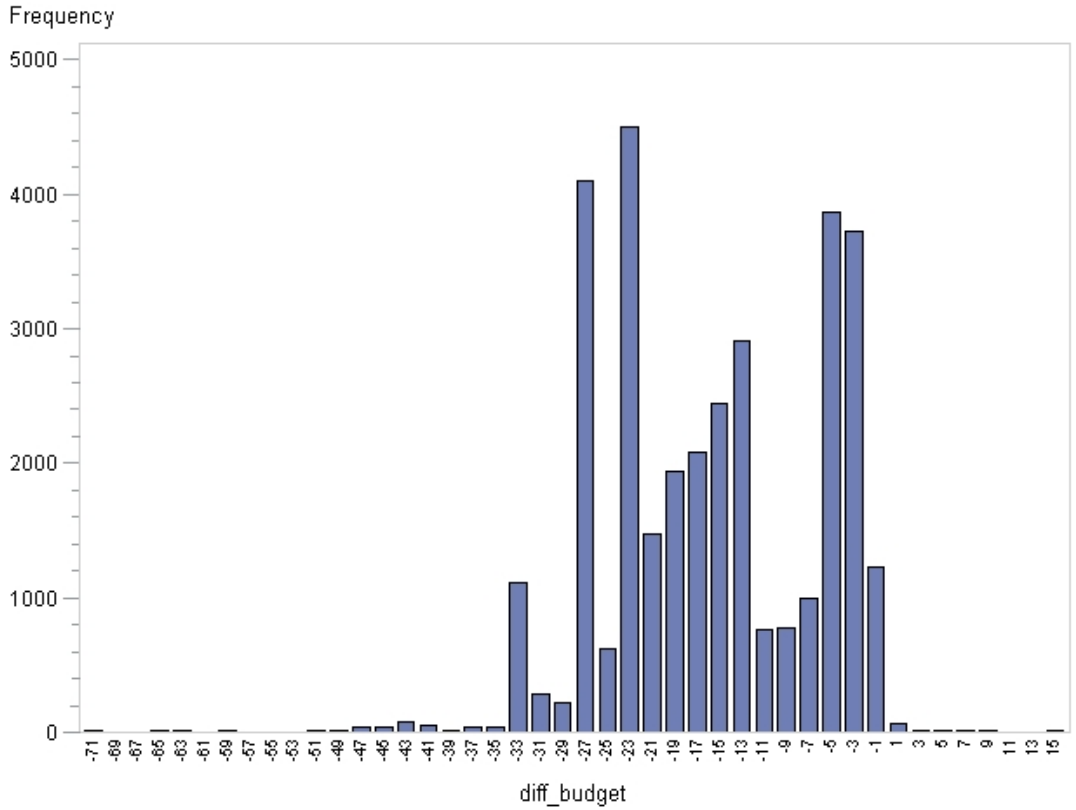
[1] *In French Service de contrôle Médical; in Dutch Dienst Geneeskundige Controle*
[2] *In French Service public fédéral Sécurité sociale; in Dutch Federale Overheidsdienst Sociale Zekerheid*
[3] *Measure based on: 1) disability level; 2) impact of handicap on learning and social skills ; 3) family's efforts on dealing with the handicap (http://handicap.fgov.be/fr/news/index.htm)*
[4] *In French indemnités d'invalidité; in Dutch invaliditeitsuitkeringen.*
[5] *Detailed information on the 99 categories can be found in the EPS lay-outs (http://www.riziv.be/information/nl/sampling/index.htm(Dutch); http://www.riziv.be/information/fr/sampling/index.htm(French).*
[6] *Receiving an income guarantee for the elderly (in French Droit au revenu minimum garanti aux personnes âgées ou garantie de revenus aux personnes âgées - in Dutch Recht op gewaarborgd inkomen voor bejaarden). Subsistence level income (in French Droit au revenu de moyens d'existence ou Minimex (CPAS) ou revenu d'intégration sociale – in Dutch Recht op minimaal leefloon of bestaansminimum (OCMW) of sociale integratieinkomens).*

APPENDIX 3. DISTRIBUTIONS OF DIFFERENCES BETWEEN SIMULATED COST SHARES AND BASELINE COST SHARES BY NUMBER OF PACKAGES PER TREATMENT EPISODE

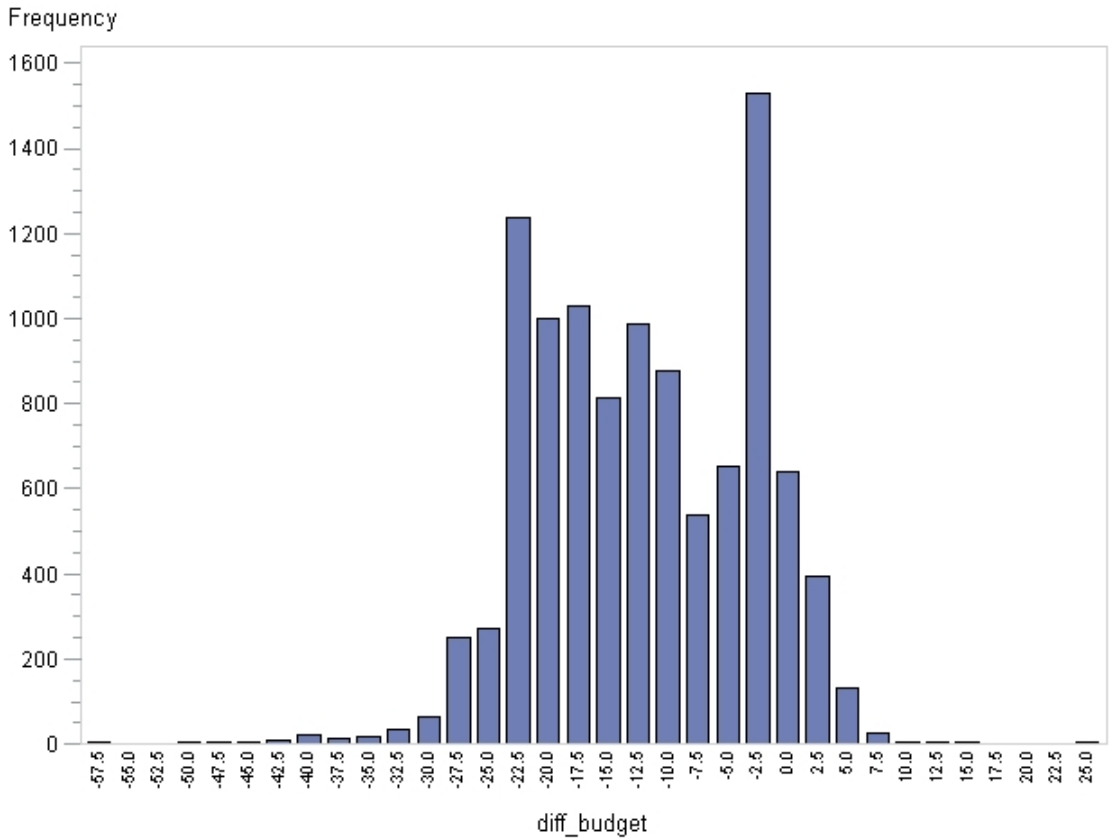
Distributions of the differences in cost sharing between simulation 1 or 2 and baseline: a negative difference ("diff_budget" variable) means the patient pays more in the simulation than in the baseline scenario.

Appendix 3.1. Scenario 1

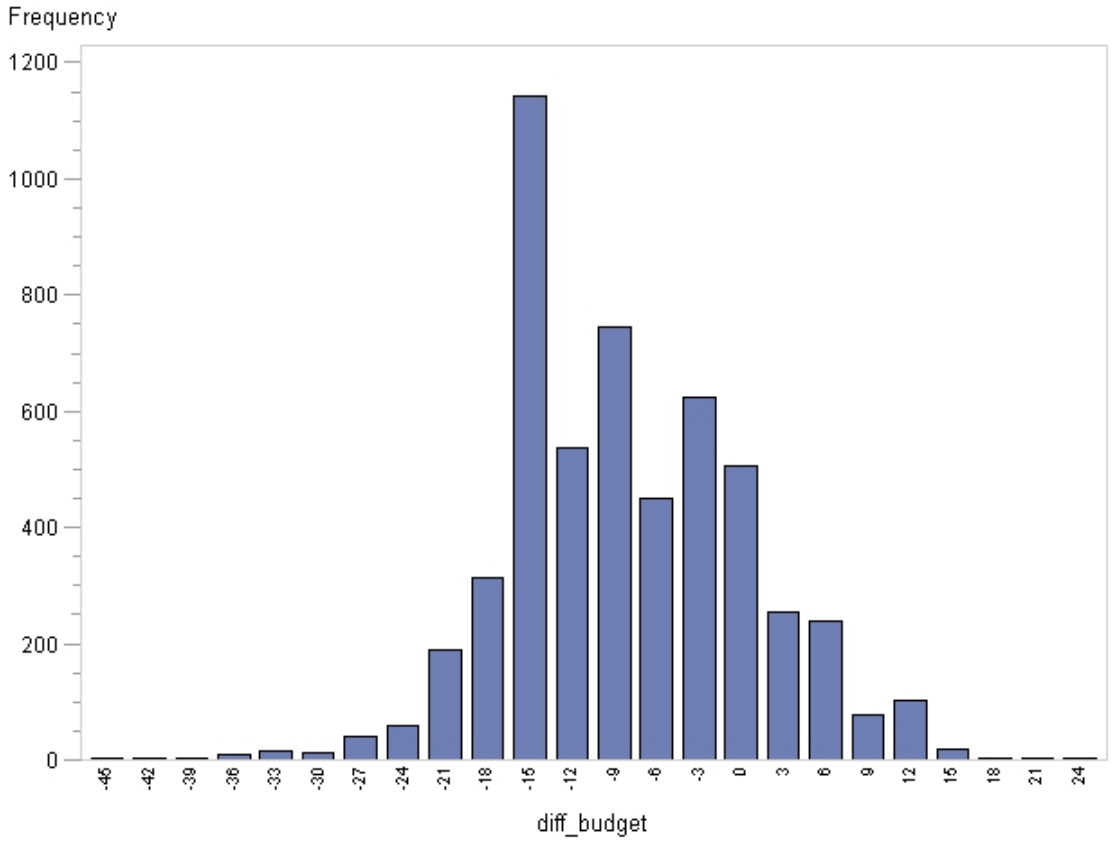
Packages = 1



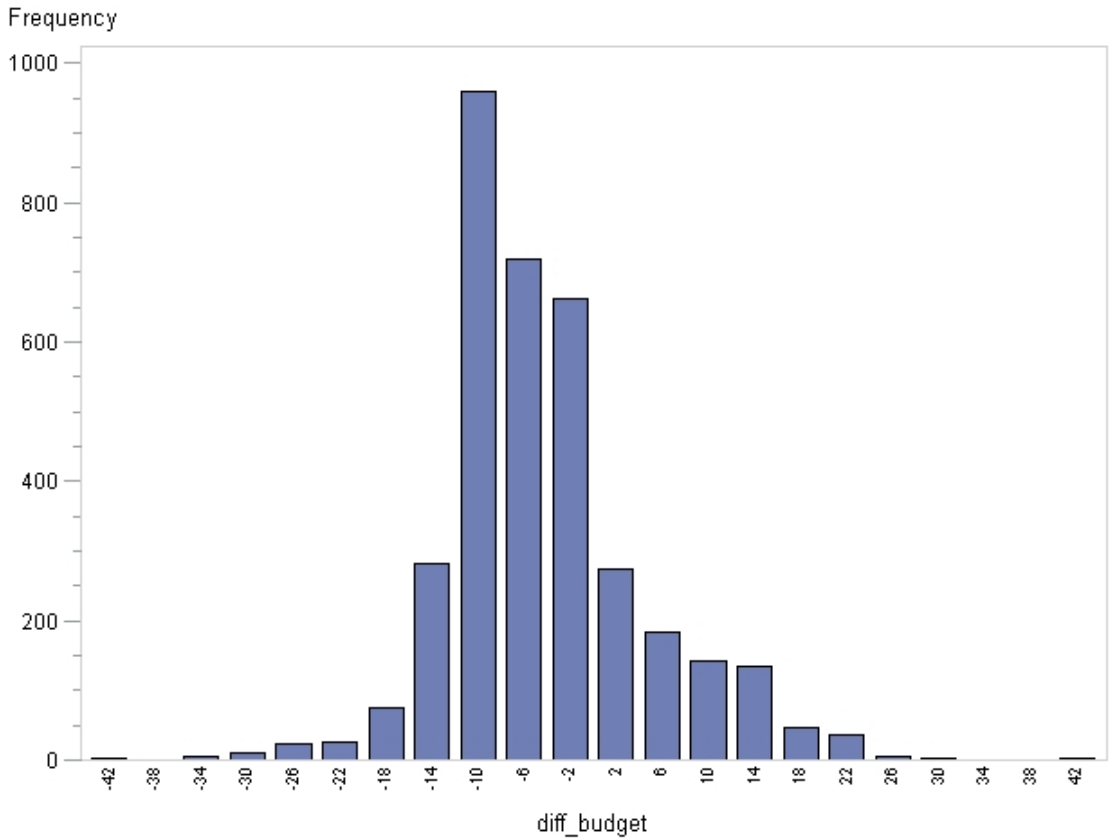
Packages = 2


Frequency
1600
1400
1200
1000
800
600
400
200
0
-57.5
-55.0
-52.5
-50.0
-47.5
-45.0
-42.5
-40.0
-37.5
-35.0
-32.5
-30.0
-27.5
-25.0
-22.5
-20.0
-17.5
-15.0
-12.5
-10.0
-7.5
-5.0
-2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
17.5
20.0
22.5
25.0
diff_budget

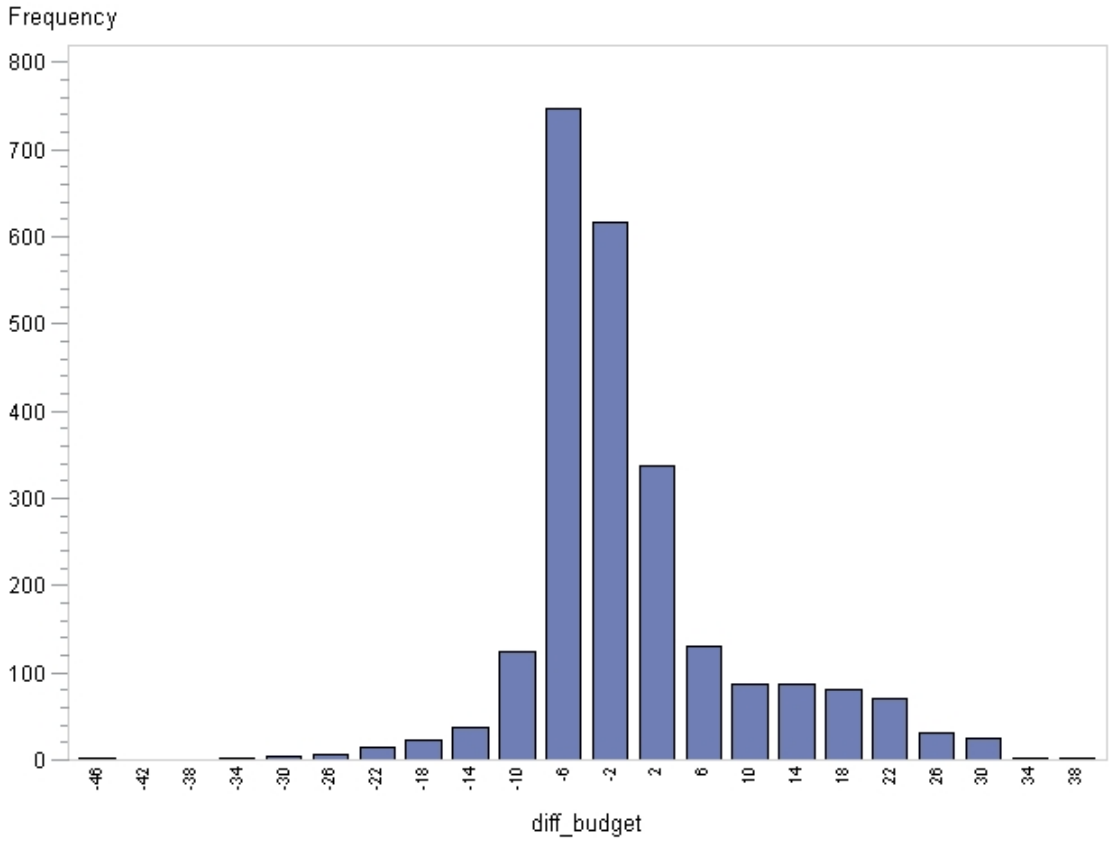
Packages = 3


Frequency
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800
600
400
200
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-45
-42
-39
-36
-33
-30
-27
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3
6
9
12
15
18
21
24
diff_budget

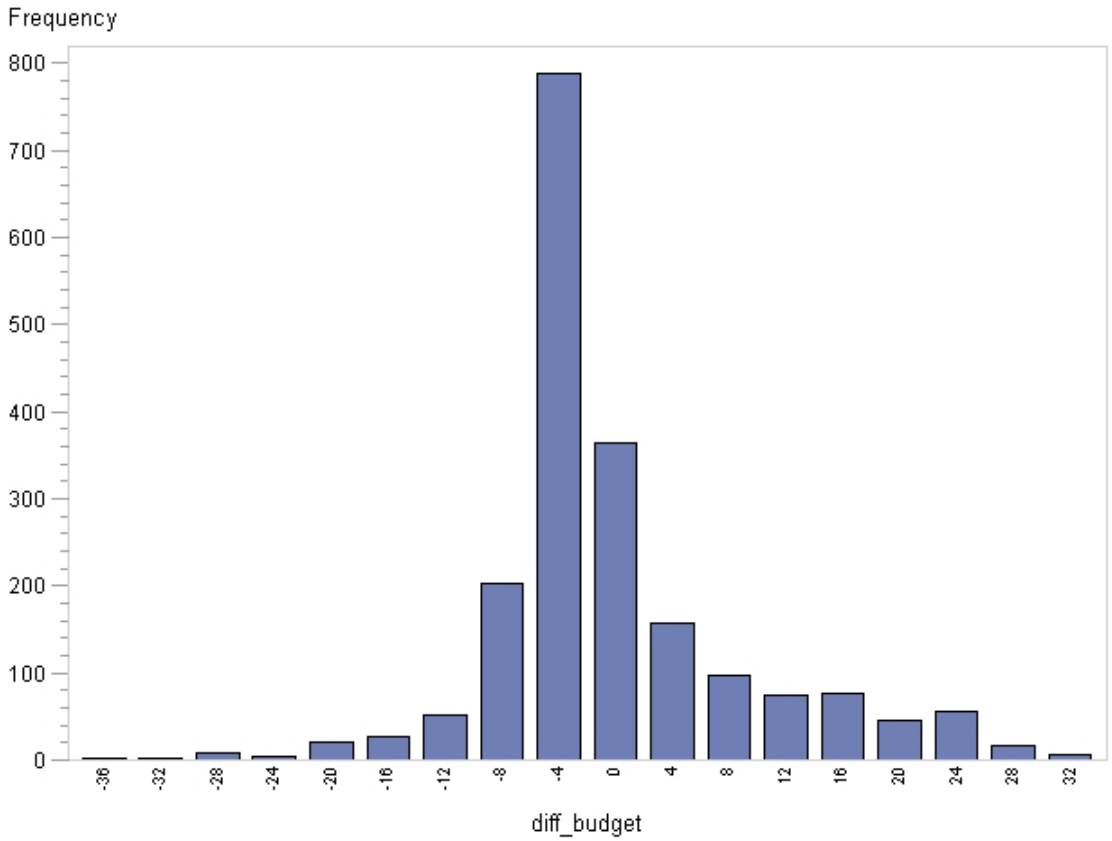
Packages = 4


Frequency
1000
800
600
400
200
0
-42
-38
-34
-30
-26
-22
-18
-14
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30
34
38
42
diff_budget

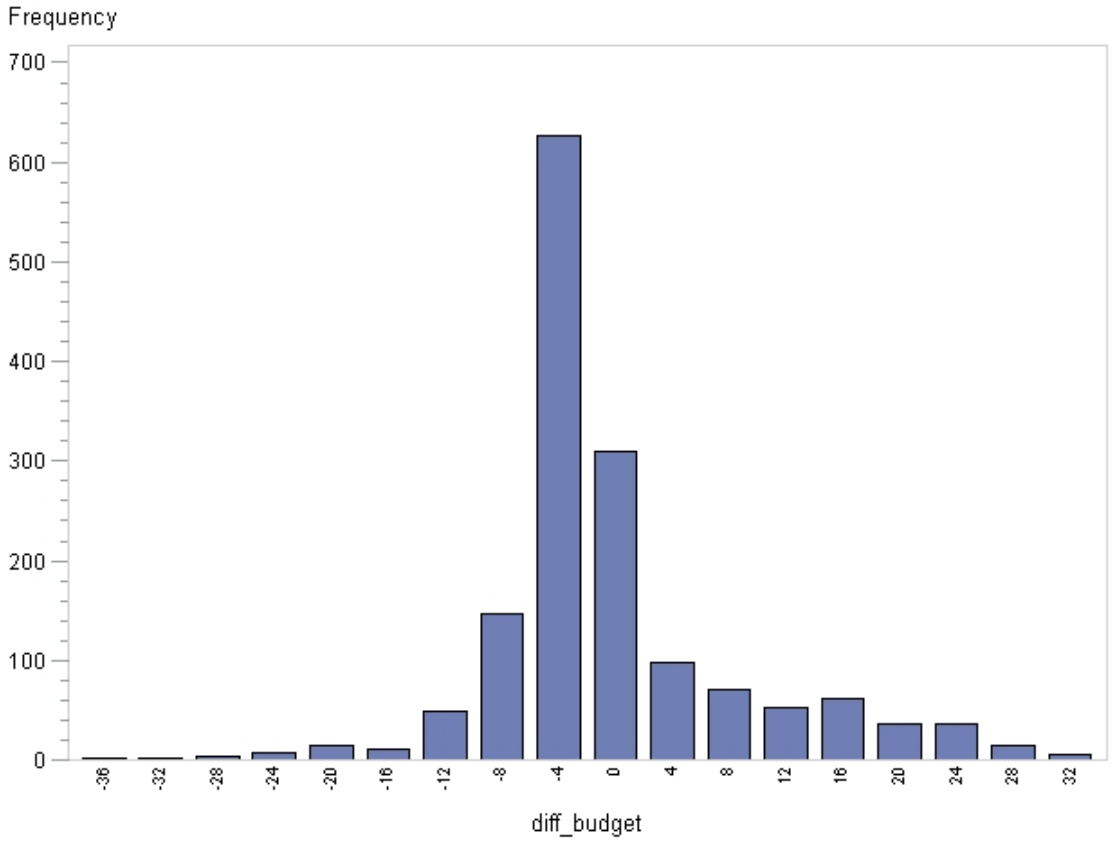
Packages = 5


Frequency
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700
600
500
400
300
200
100
0
-46
-42
-38
-34
-30
-26
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26
30
34
38
diff_budget

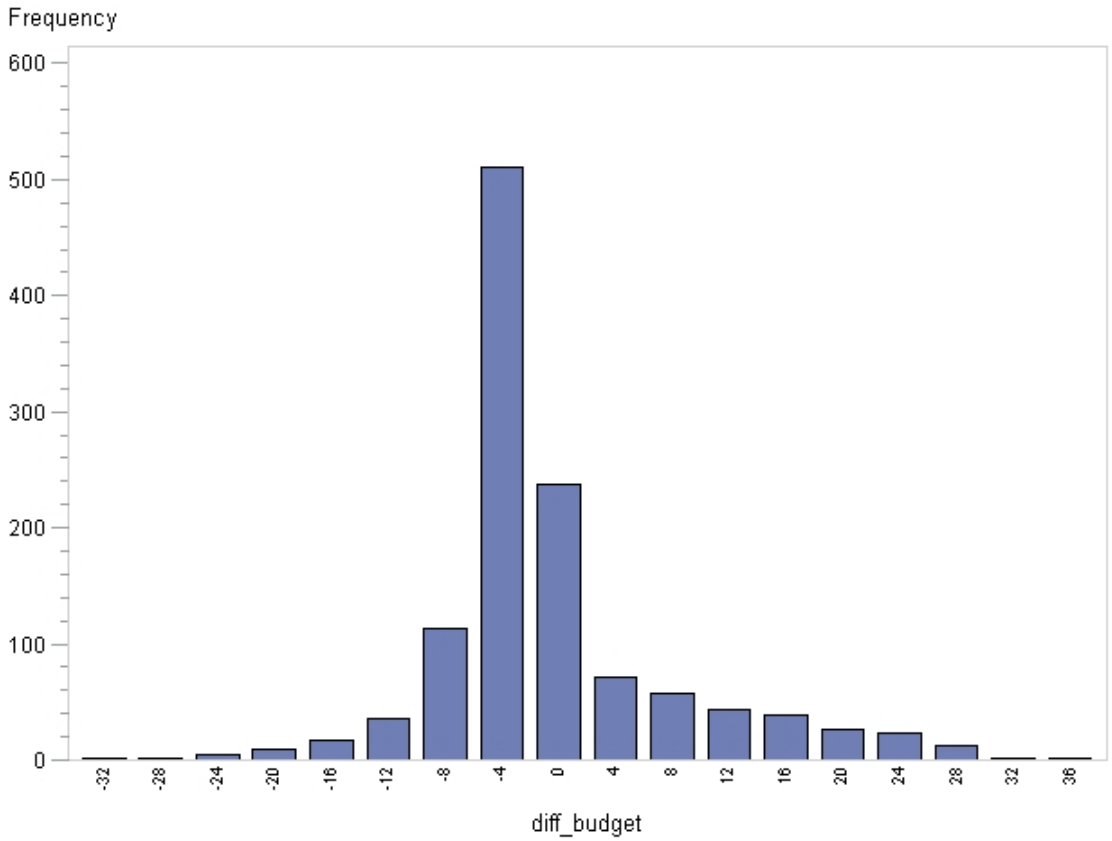
Packages = 6


Frequency
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700
600
500
400
300
200
100
0
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-32
-28
-24
-20
-16
-12
-8
-4
0
4
8
12
16
20
24
28
32
diff_budget

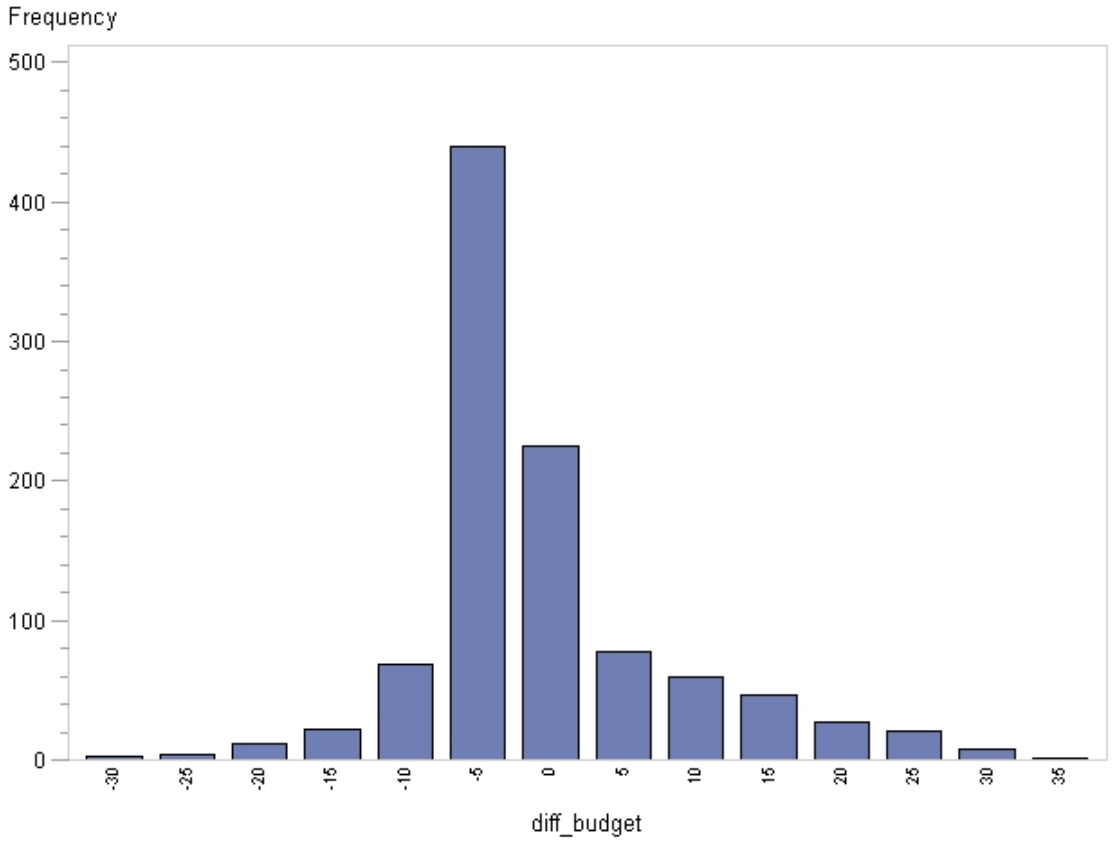
Packages = 7


Frequency
700
600
500
400
300
200
100
0
-36
-32
-28
-24
-20
-16
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20
24
28
32
diff_budget

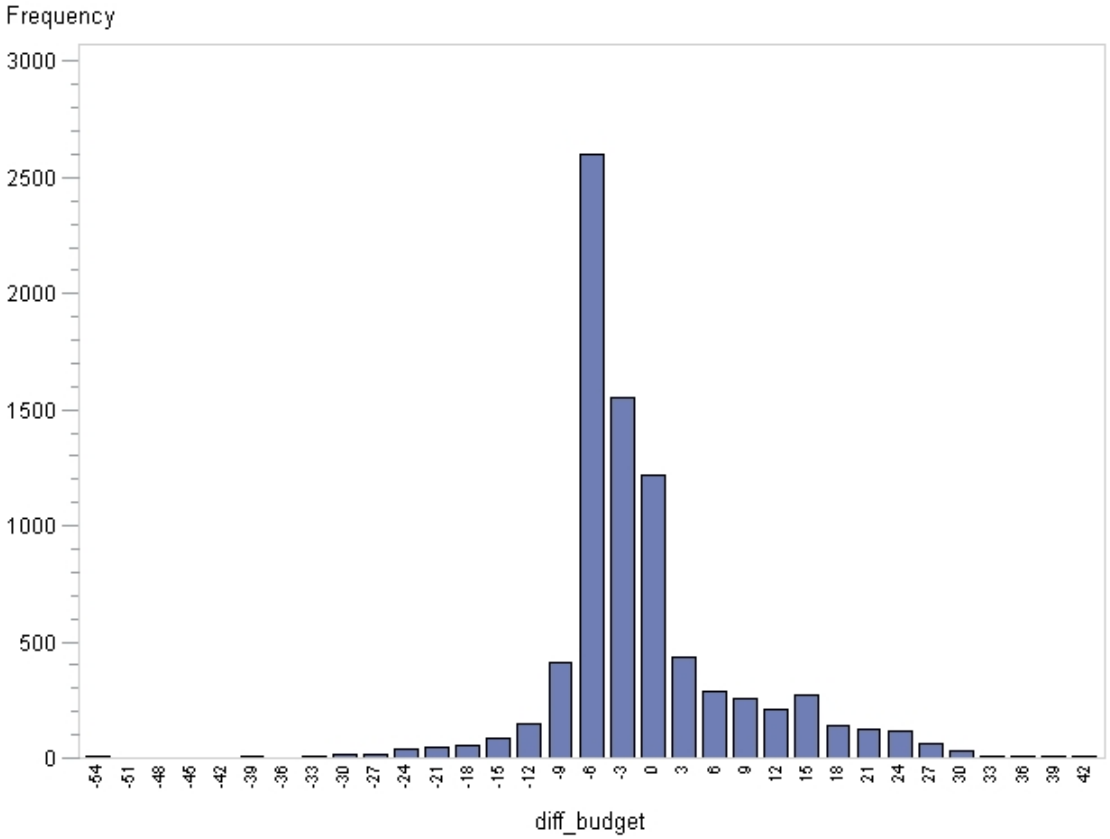
Packages = 8


Frequency
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500
400
300
200
100
0
-32
-28
-24
-20
-16
-12
-8
-4
0
4
8
12
16
20
24
28
32
36
diff_budget

Packages = 9

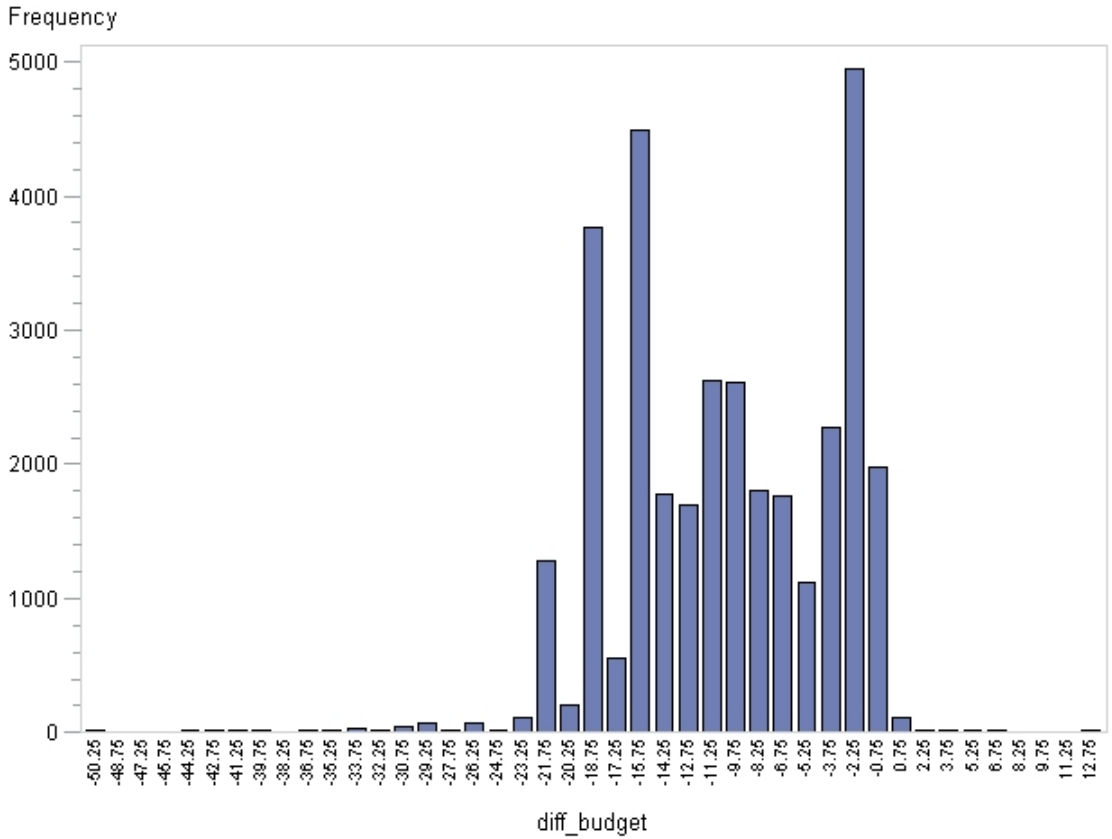

Frequency
500
400
300
200
100
0
-30
-25
-20
-15
-10
-5
0
5
10
15
20
25
30
35
diff_budget

Packages ≥ 10

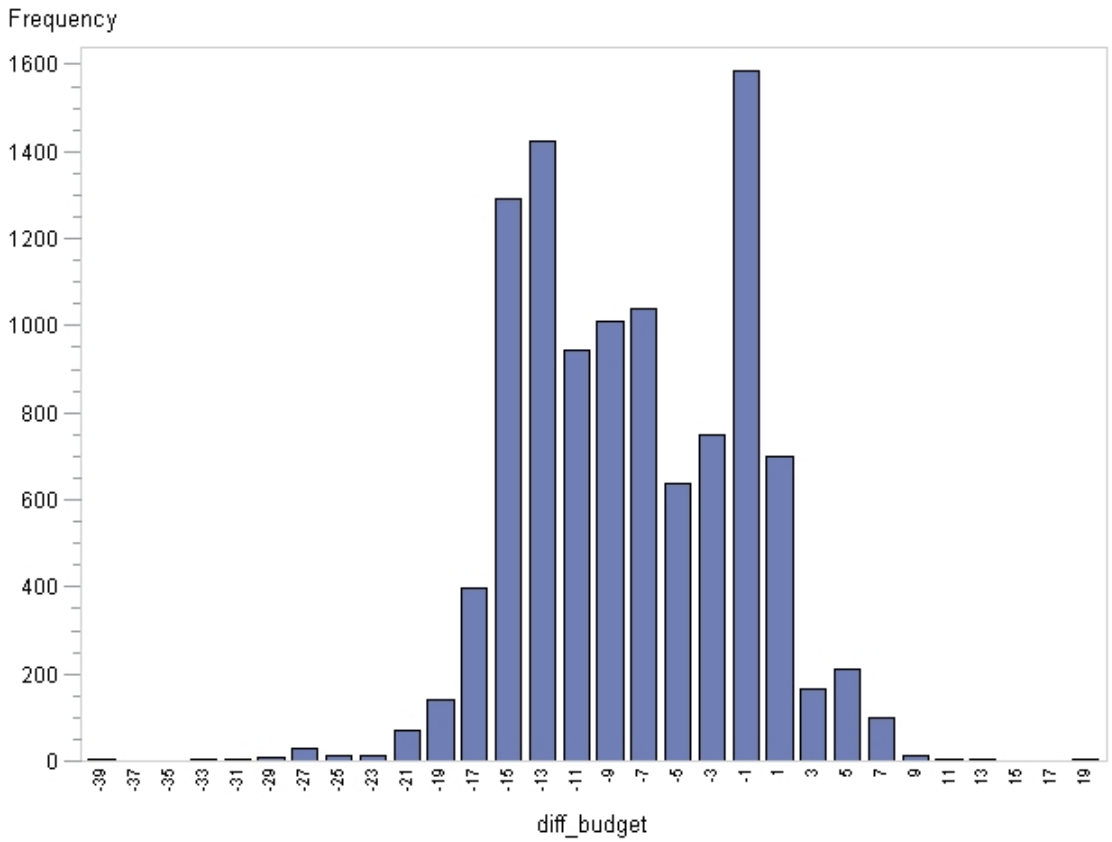

Frequency
3000
2500
2000
1500
1000
500
0
-54
-51
-48
-45
-42
-39
-36
-33
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-27
-24
-21
-18
-15
-12
-9
-6
-3
0
3
6
9
12
15
18
21
24
27
30
33
36
39
42
diff_budget

Appendix 3.2. Scenario 2

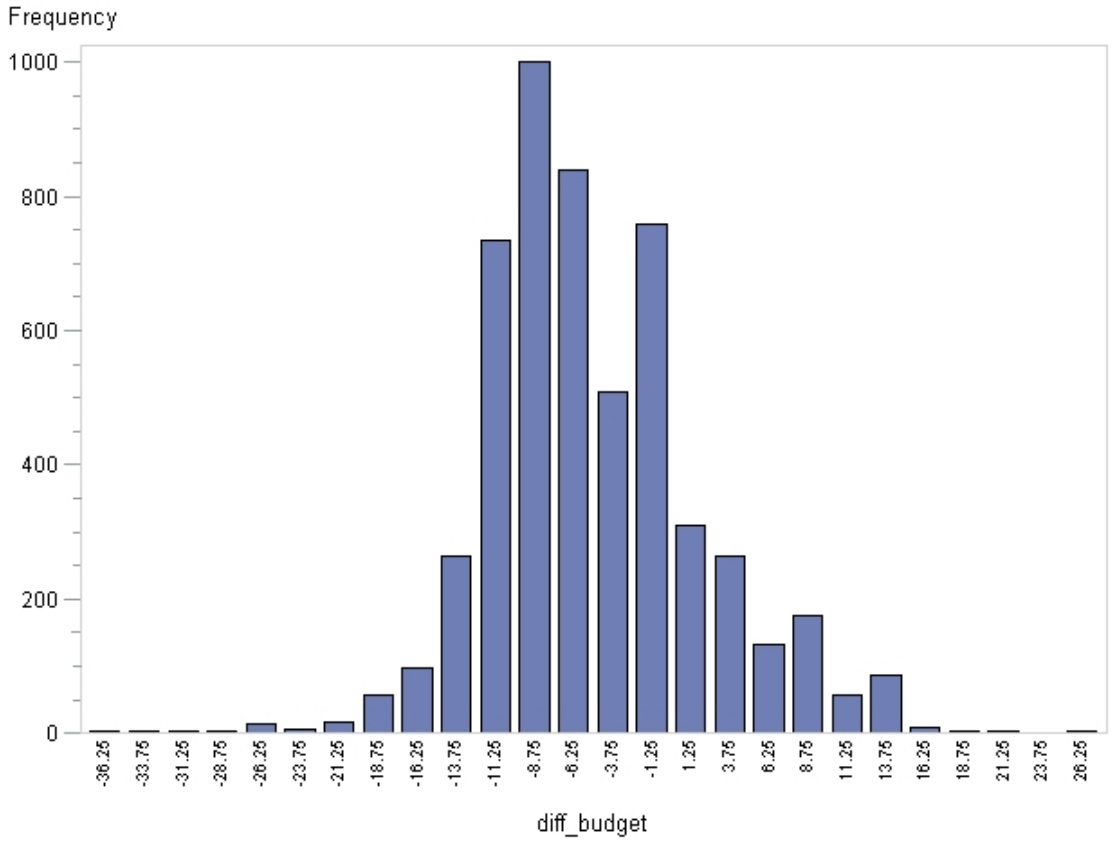
Packages = 1



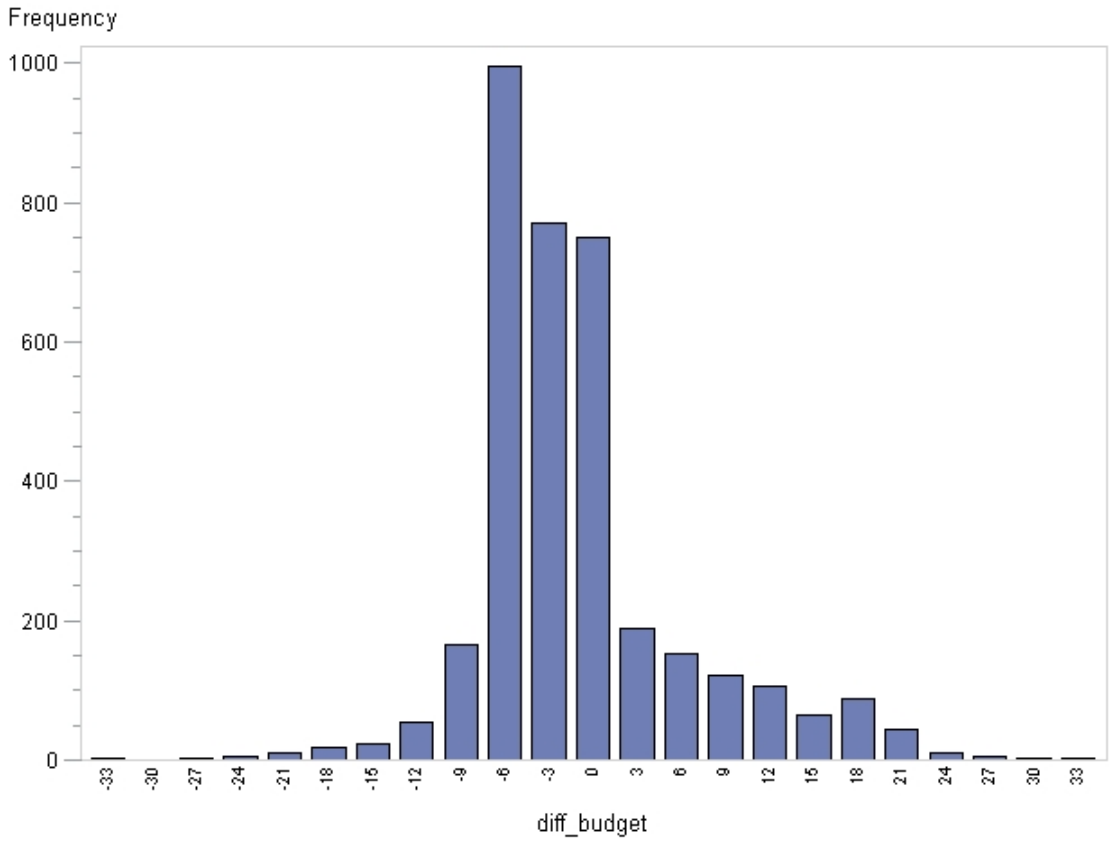
Packages = 2


Frequency
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1400
1200
1000
800
600
400
200
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-39
-37
-35
-33
-31
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-27
-25
-23
-21
-19
-17
-15
-13
-11
-9
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-5
-3
-1
1
3
5
7
9
11
13
15
17
19
diff_budget

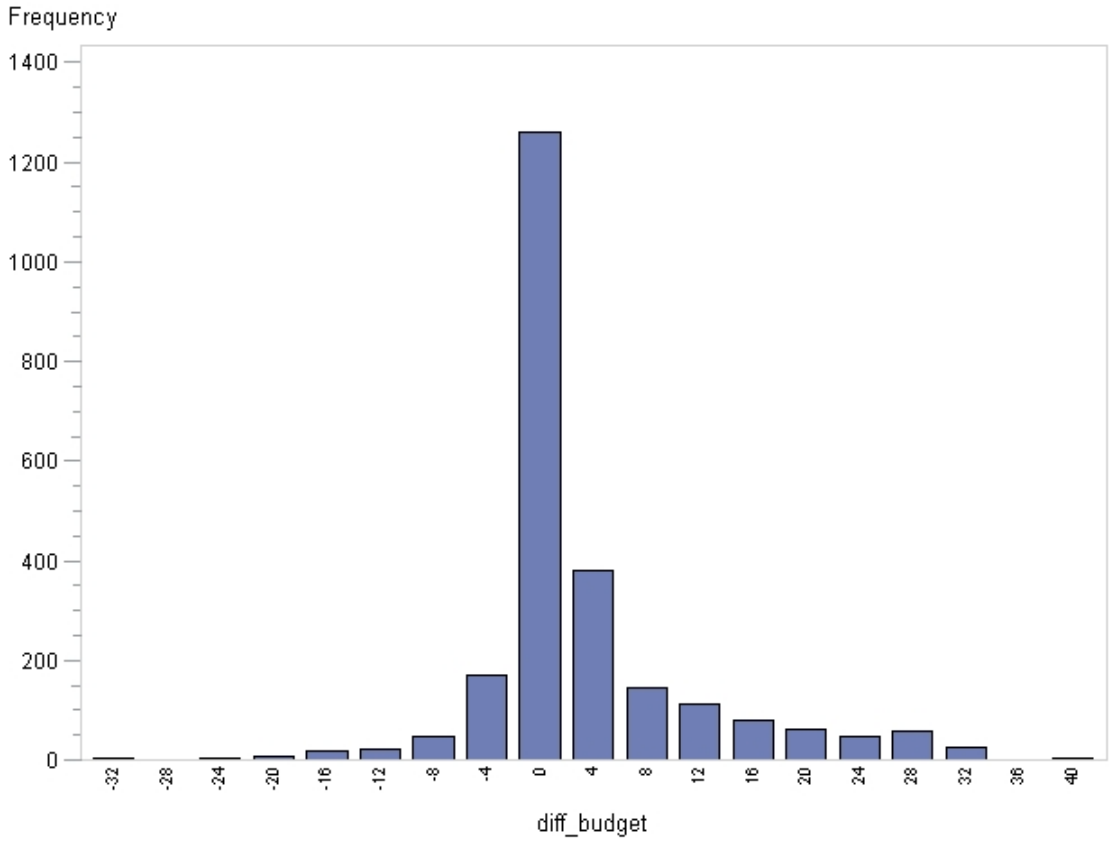
Packages = 3


Frequency
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800
600
400
200
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-36.25
-33.75
-31.25
-28.75
-26.25
-23.75
-21.25
-18.75
-16.25
-13.75
-11.25
-8.75
-6.25
-3.75
-1.25
1.25
3.75
6.25
8.75
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21.25
23.75
26.25
diff_budget

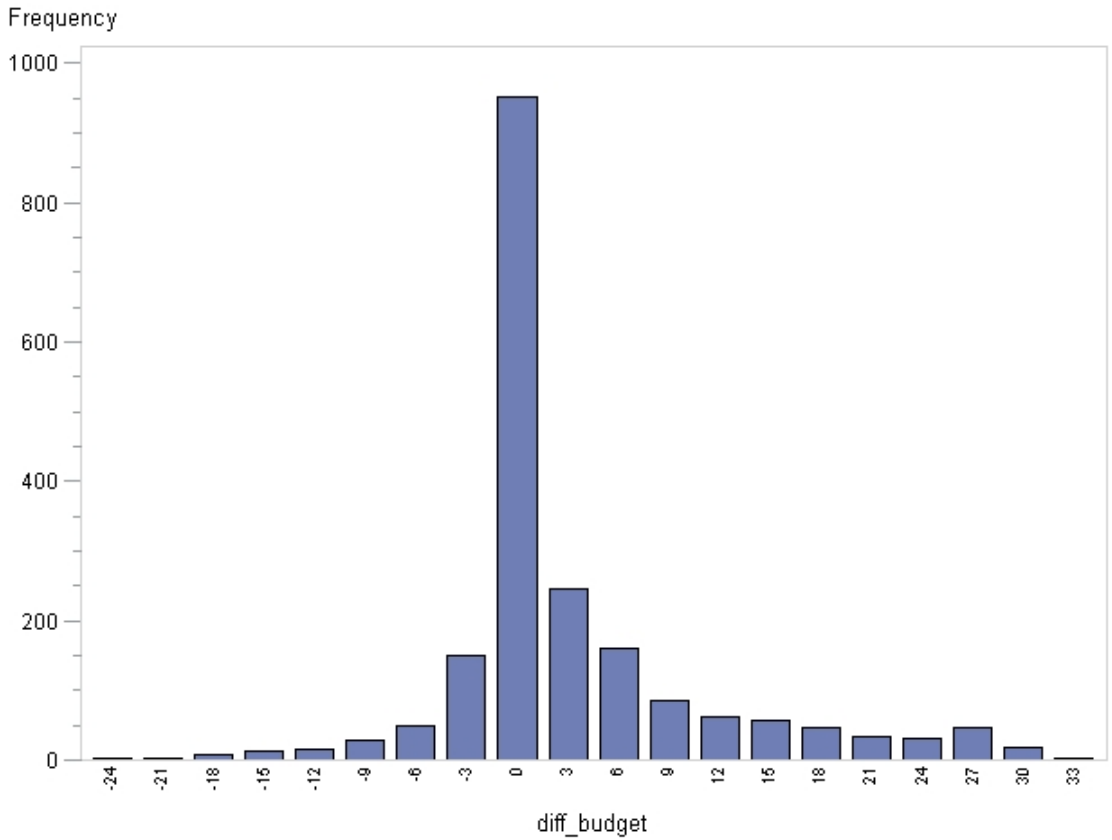
Packages = 4


Frequency
1000
800
600
400
200
0
-33
-30
-27
-24
-21
-18
-15
-12
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-6
-3
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3
6
9
12
15
18
21
24
27
30
33
diff_budget

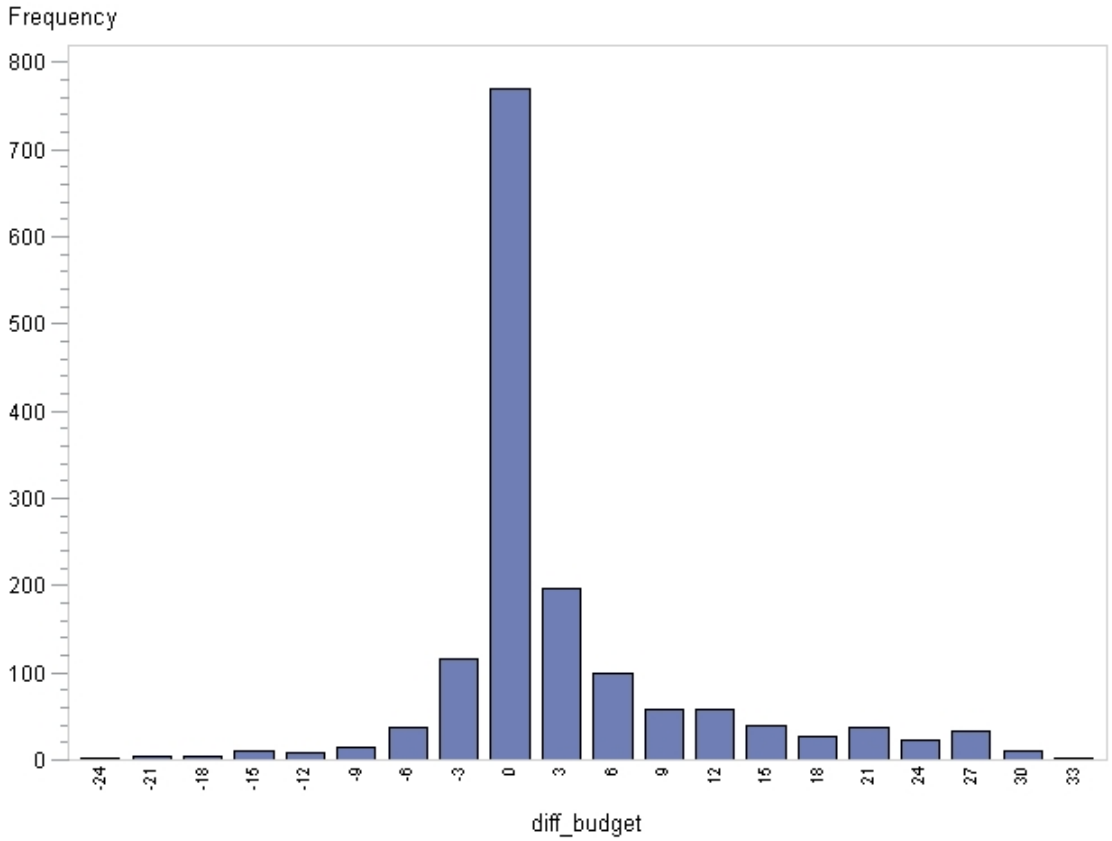
Packages = 5


Frequency
1400
1200
1000
800
600
400
200
0
-32
-28
-24
-20
-16
-12
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4
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24
28
32
36
40
diff_budget

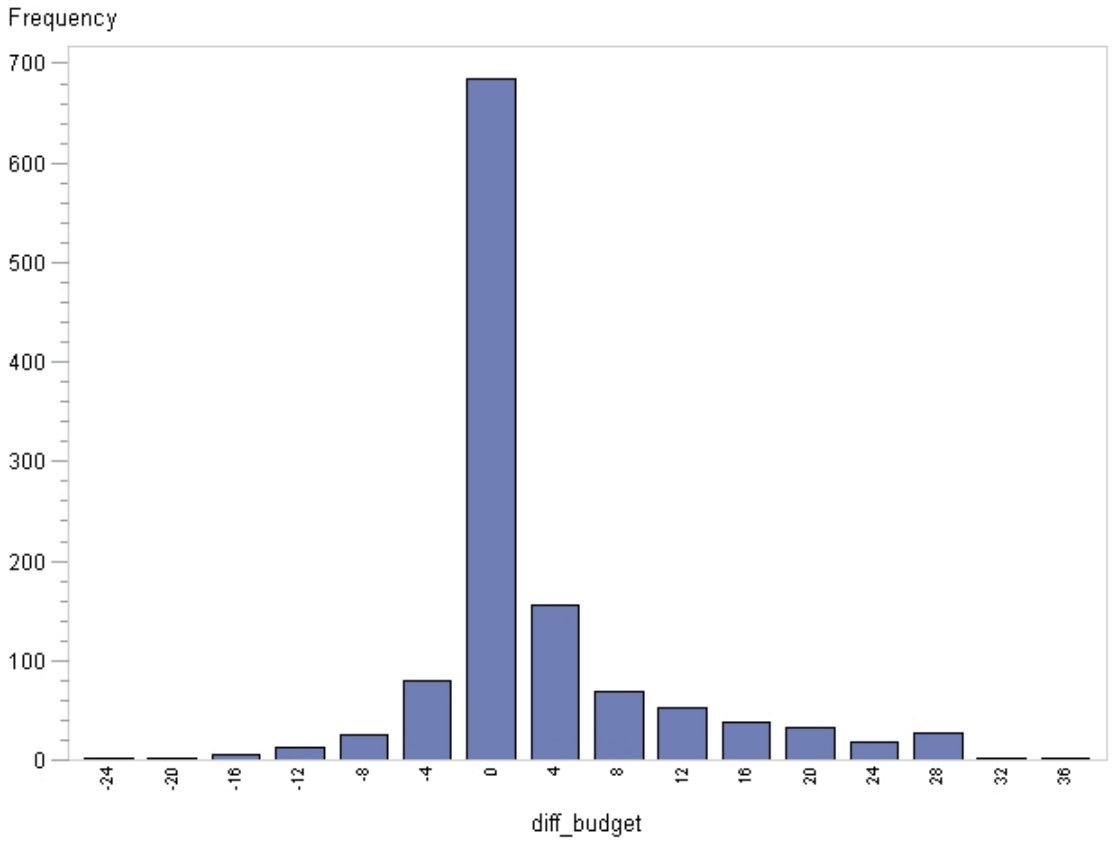
Packages = 6


Frequency
1000
800
600
400
200
0
-24
-21
-18
-15
-12
-9
-6
-3
0
3
6
9
12
15
18
21
24
27
30
33
diff_budget

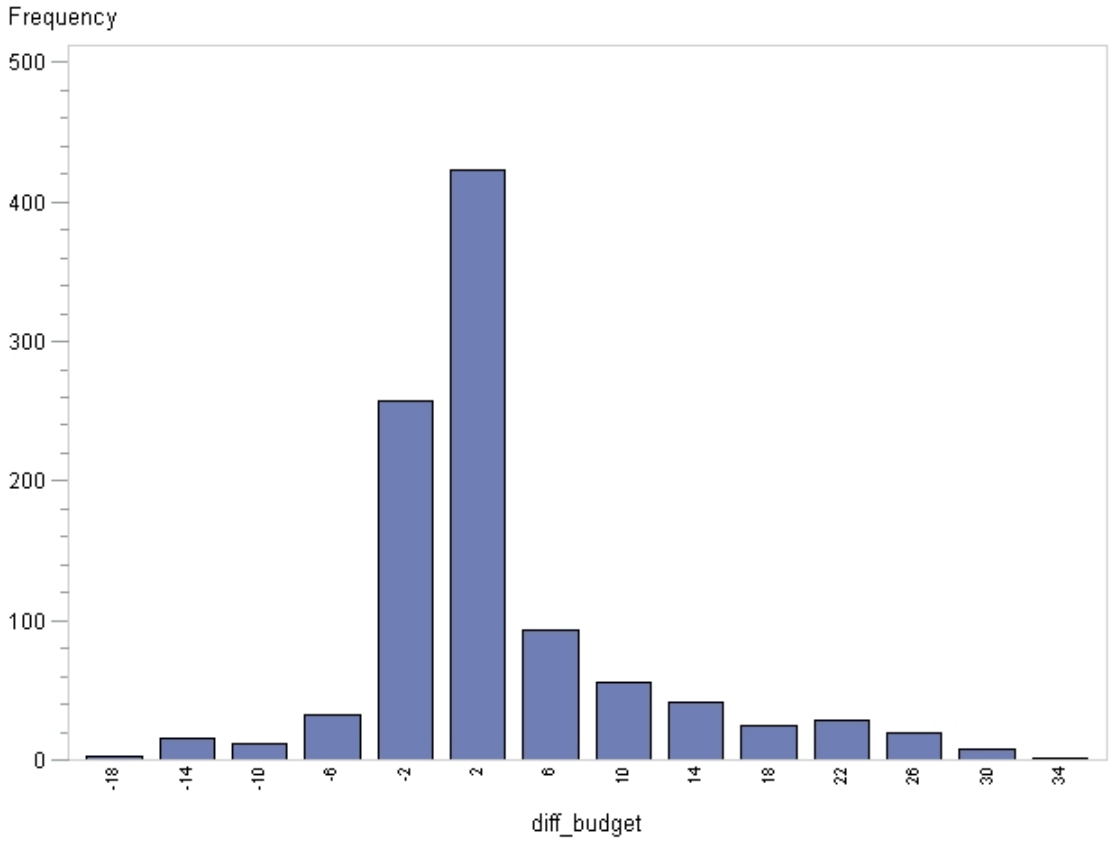
Packages = 7


Frequency
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700
600
500
400
300
200
100
0
-24
-21
-18
-15
-12
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-6
-3
0
3
6
9
12
15
18
21
24
27
30
33
diff_budget

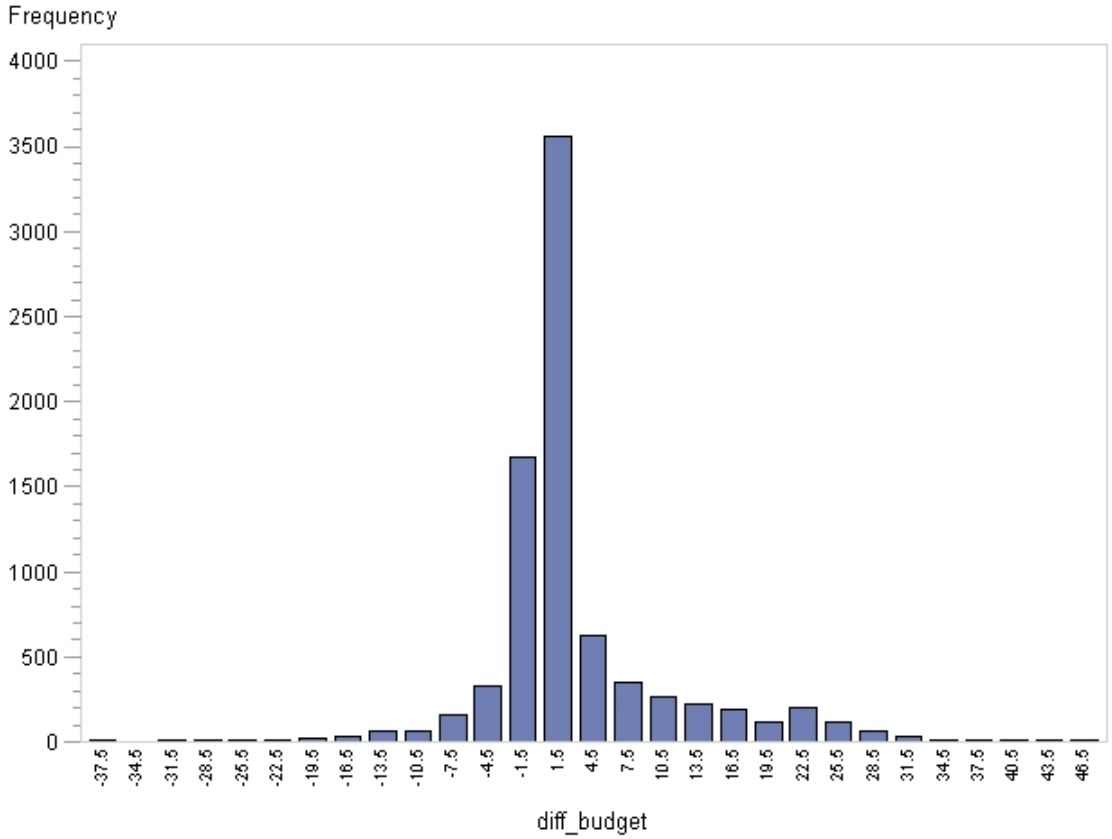
Packages = 8


Frequency
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600
500
400
300
200
100
0
-24
-20
-16
-12
-8
-4
0
4
8
12
16
20
24
28
32
36
diff_budget

Packages = 9


Frequency
500
400
300
200
100
0
-18
-14
-10
-6
-2
2
6
10
14
18
22
26
30
34
diff_budget

Packages ≥ 10


Frequency
4000
3500
3000
2500
2000
1500
1000
500
0
-37.5
-34.5
-31.5
-28.5
-25.5
-22.5
-19.5
-16.5
-13.5
-10.5
-7.5
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4.5
7.5
10.5
13.5
16.5
19.5
22.5
25.5
28.5
31.5
34.5
37.5
40.5
43.5
46.5
diff_budget

APPENDIX 4. SIMULATION RESULTS FOR DIFFERENT SUBGROUPS

Table 26 – Simulation results of scenario 1 for different subgroups

Preferential reimbursement	Yes				No			
Variable	N*	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	588 240	21.60	6.33	43.54	2 306 800	30.15	9.85	56.62
Patient share simulated	588 240	26.22	17.92	41.06	2 306 800	41.55	31.37	54.20
Difference between patient share and simulation	588 240	-4.62	-3.33	8.53	2 306 800	-11.40	-10.57	11.29

Low income	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	116 680	19.84	6.43	40.55	2 778 360	28.77	9.10	54.80
Patient share simulated	116 680	25.31	17.95	38.22	2 778 360	38.98	28.85	52.60
Difference between patient share and simulation	116 680	-5.47	-3.81	9.02	2 778 360	-10.21	-8.28	11.17

Lump sum B or C	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	36 000	30.65	8.80	58.66	2 859 040	28.38	9.10	54.27
Patient share simulated	36 000	35.14	19.66	56.93	2 859 040	38.47	28.53	52.10
Difference between patient share and simulation	36 000	-4.49	-2.89	10.34	2 859 040	-10.09	-8.10	11.12

Having a chronical illness	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	309 560	28.30	7.95	56.13	2 585 480	28.43	9.10	54.11
Patient share simulated	309 560	33.53	19.08	54.15	2 585 480	39.02	29.50	51.89
Difference between patient share and simulation	309 560	-5.23	-3.27	9.88	2 585 480	-10.60	-9.18	11.13

Disability	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	57 800	27.35	8.65	53.79	2 837 240	28.43	9.10	54.34
Patient share simulated	57 800	32.25	19.08	51.57	2 837 240	38.56	28.53	52.17
Difference between patient share and simulation	57 800	-4.90	-3.57	9.58	2 837 240	-10.13	-8.17	11.13

Unemployment status	Not receiving unemployment benefits				Other benefits				Full unemployment benefit			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	2 490 040	28.79	9.10	54.97	1 480	20.52	9.10	31.87	293 080	26.15	9.10	48.45
Patient share simulated	2 490 040	38.55	28.16	52.77	1 480	31.64	28.53	29.78	293 080	37.58	29.40	46.53
Difference between patient share and simulation	2 490 040	-9.76	-7.50	11.10	1 480	-11.12	-12.38	9.57	293 080	-11.43	-10.85	11.08

Unemployment status	Partial unemployment benefit				Pre-retirement benefits			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	84 840	25.61	9.10	54.62	25 600	27.78	9.10	54.43
Patient share simulated	84 840	38.28	30.55	52.85	25 600	37.80	27.68	52.35
Difference between patient share and simulation	84 840	-12.67	-12.38	11.15	25 600	-10.02	-8.42	11.55

Gender age (male)	M_0_19				M_20_49				M_50_64			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	19 760	14.00	7.13	26.16	420 600	25.71	9.10	48.50	304 120	27.15	9.10	52.88
Patient share simulated	19 760	24.24	20.64	26.68	420 600	37.36	29.92	46.63	304 120	37.53	28.77	50.85
Difference between patient share and simulation	19 760	-10.24	-7.37	10.31	420 600	-11.64	-11.17	10.97	304 120	-10.38	-8.64	11.31

Gender age (male)	M_65_74				M_74_85				M_85+			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	129 600	25.46	9.05	54.39	134 440	27.32	9.05	54.48	72 560	28.02	8.74	53.14
Patient share simulated	129 600	34.51	23.80	52.30	134 440	35.28	23.56	52.48	72 560	34.15	20.99	51.32
Difference between patient share and simulation	129 600	-9.05	-6.02	11.35	134 440	-7.95	-5.44	11.45	72 560	-6.14	-3.92	10.57

Gender age (female)	F_0_19				F_20_49				F_50_64			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	24 240	14.22	7.33	26.27	741 520	29.52	10.20	52.73	468 040	30.01	9.13	57.30
Patient share simulated	24 240	25.68	23.30	25.90	741 520	41.13	31.75	50.31	468 040	40.17	28.77	55.00
Difference between patient share and simulation	24 240	-11.45	-10.59	10.24	741 520	-11.61	-10.85	10.90	468 040	-10.16	-7.86	11.10

Gender age (female)	F_65_74				F_74_85				F_85+			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	214 400	26.13	9.10	49.41	215 800	29.64	8.77	60.95	149 960	37.47	9.53	69.98
Patient share simulated	214 400	35.14	24.94	47.13	215 800	37.46	22.69	58.89	149 960	42.86	21.71	67.76
Difference between patient share and simulation	214 400	-9.02	-6.56	10.90	215 800	-7.83	-5.44	10.69	149 960	-5.39	-3.56	10.54

** N=number of treatment episodes*

Table 27 – Simulation results of scenario 2 for different subgroups

Preferential reimbursement	Yes				No			
Variable	N*	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	588 240	21.60	6.33	43.54	2 306 800	30.15	9.85	56.62
Patient share simulated	588 240	23.61	13.64	40.83	2 306 800	36.75	23.85	53.83
Difference between patient share and simulation	588 240	-2.00	-1.50	7.34	2 306 800	-6.60	-5.98	8.79

Low income	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	116 680	19.84	6.43	40.55	2 778 360	28.77	9.10	54.80
Patient share simulated	116 680	22.49	13.67	37.86	2 778 360	34.56	22.73	52.17
Difference between patient share and simulation	116 680	-2.65	-1.90	7.49	2 778 360	-5.79	-4.76	8.74

Lump sum B or C	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	36 000	30.65	8.80	58.66	2 859 040	28.38	9.10	54.27
Patient share simulated	36 000	32.29	16.29	56.33	2 859 040	34.10	22.47	51.66
Difference between patient share and simulation	36 000	-1.63	-0.45	8.72	2 859 040	-5.72	-4.64	8.70

Having a chronical illness	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	309 560	28.30	7.95	56.13	2 585 480	28.43	9.10	54.11
Patient share simulated	309 560	30.64	14.96	53.65	2 585 480	34.49	22.73	51.47
Difference between patient share and simulation	309 560	-2.33	-1.07	8.13	2 585 480	-6.06	-5.14	8.70

Disability	Yes				No			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	57 800	27.35	8.65	53.79	2 837 240	28.43	9.10	54.34
Patient share simulated	57 800	29.43	14.65	51.22	2 837 240	34.17	22.60	51.73
Difference between patient share and simulation	57 800	-2.08	-1.33	8.06	2 837 240	-5.74	-4.66	8.71

Unemployment status	Not receiving unemployment benefits				Other benefits				Full unemployment benefit			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	2 490 040	28.79	9.10	54.97	1 480	20.52	9.10	31.87	293 080	26.15	9.10	48.45
Patient share simulated	2 490 040	34.26	22.40	52.33	1 480	27.19	21.40	29.34	293 080	32.89	22.73	46.05
Difference between patient share and simulation	2 490 040	-5.47	-4.12	8.72	1 480	-6.68	-8.05	7.18	293 080	-6.75	-6.49	8.58

Unemployment status	Partial unemployment benefit				Pre-retirement benefits			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	84 840	25.61	9.10	54.62	25 600	27.78	9.10	54.43
Patient share simulated	84 840	33.30	23.85	52.47	25 600	33.36	21.58	51.82
Difference between patient share and simulation	84 840	-7.69	-8.26	8.48	25 600	-5.58	-4.97	9.16

Gender age (male)	M_0_19				M_20_49				M_50_64			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	19 760	14.00	7.13	26.16	420 600	25.71	9.10	48.50	304 120	27.15	9.10	52.88
Patient share simulated	19 760	20.31	15.80	25.38	420 600	32.61	22.73	46.14	304 120	33.06	22.60	50.36
Difference between patient share and simulation	19 760	-6.30	-4.72	7.55	420 600	-6.90	-6.57	8.40	304 120	-5.91	-4.93	8.81

Gender age (male)	M_65_74				M_74_85				M_85+			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	129 600	25.46	9.05	54.39	134 440	27.32	9.05	54.48	72 560	28.02	8.74	53.14
Patient share simulated	129 600	30.50	18.91	51.81	134 440	31.47	18.95	51.93	72 560	30.97	16.38	50.68
Difference between patient share and simulation	129 600	-5.04	-3.44	8.94	134 440	-4.14	-2.90	9.21	72 560	-2.96	-1.01	8.46

Gender age (female)	F_0_19				F_20_49				F_50_64			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	24 240	14.22	7.33	26.27	741 520	29.52	10.20	52.73	468 040	30.01	9.13	57.30
Patient share simulated	24 240	21.36	17.89	24.77	741 520	36.28	23.85	49.97	468 040	35.72	22.73	54.62
Difference between patient share and simulation	24 240	-7.14	-6.57	7.51	741 520	-6.76	-6.49	8.47	468 040	-5.72	-4.43	8.73

Gender age (female)	F_65_74				F_74_85				F_85+			
Variable	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev	N	Mean	Median	Std Dev
Patient share	214 400	26.13	9.10	49.41	215 800	29.64	8.77	60.95	149 960	37.47	9.53	69.98
Patient share simulated	214 400	31.10	20.05	46.67	215 800	33.79	17.85	58.45	149 960	39.68	17.17	67.30
Difference between patient share and simulation	214 400	-4.98	-3.54	8.64	215 800	-4.15	-2.70	8.55	149 960	-2.21	-0.84	8.80

**N=number of treatment episodes*

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