KCE REPORT 195A

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

MODELLEN VOOR BURGER- EN PATIËNTENPARTICIPATIE IN HET GEZONDHEIDSZORGBELEID

DEEL 1: VERKENNING VAN DE HAALBAARHEID EN AANVAARDBAARHEID





Het Federaal Kenniscentrum voor de Gezondheidszorg

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DEEL 1: VERKENNING VAN DE HAALBAARHEID EN AANVAARDBAARHEID

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VOORWOORD

Moet men zich noodzakelijkerwijze beklagen over een situatie of een systeem om het te willen verbeteren? Is het noodzakelijk om ervan uit te gaan dat de keuzen die we maken in de gezondheidszorg betwistbaar zijn, om het keuzeproces te willen verbeteren? Uiteraard niet. Het volstaat om ervan overtuigd te zijn dat reeds de loutere deelname aan een proces met een maatschappelijk en dus politiek karakter een breder draagvlak kan creëren voor de resultaten van dit proces.

Opdat burgers, die nu en dan ook patiënten zijn, zich zouden terugvinden in beslissingen met betrekking tot de terugbetaling van gezondheidsproducten en –diensten, dienen ze wellicht best betrokken te worden bij deze beslissingen, die uiteindelijk in eerste instantie hen aanbelangen. Maar de meest perfecte scenario's voor burger- en patiëntenbetrokkenheid zullen falen indien degenen die momenteel de beslissingen nemen het niet eens zijn met het principe om hierin ook burgers en patiënten te betrekken.

Dat is precies wat we in deze studie wilden nagaan: in hoeverre is het betrekken van burgers en patiënten in het besluitvormingsproces aanvaardbaar voor de huidige spilfiguren in de keuzeprocessen met betrekking tot prioriteiten in de gezondheidszorg. En wat is de visie bij degenen die nog niet bij deze keuzeprocessen betrokken zijn en het misschien wel zouden willen? De resultaten van het onderzoek wettigen een zekere hoop op verandering, ook al wil niemand echt een revolutie.

Momenteel staan burgers en patiënten misschien op de drempel van het RIZIV. De toekomst zal uitwijzen wanneer ze voluit zullen binnentreden en welke rol ze dan zullen spelen. Ook al lijkt het betrekken van burgers en patiënten een democratische evidentie, men zal voorzichtig tewerk moeten gaan en voldoende tijd moeten nemen om te leren, vooral wanneer men burgers en patiënten mede-verantwoordelijk wenst te maken voor de beslissingen die worden genomen. Hierbij is het belangrijk om de ervaringen die men opdoet met patiënten- en burgerbetrokkenheid te evalueren, niet alleen hun resultaten maar ook de procedures, die van ieder van ons een meer betrokken burger en patiënt zullen maken.

Voor dit eerste deel van een tweeledige studie naar manieren om maatschappelijke waarden mee te nemen in besluitvormingsprocessen, hebben we beroep kunnen doen op de expertise van Yellow Window. Maar bovenal hebben een groot aantal vertegenwoordigers van alle stakeholders een onmisbare bijdrage geleverd aan onze studie. Alleen al om die reden was dit een participatieve ervaring die meer dan de moeite waard was. Het vervolg op deze studie belooft niet minder boeiend te worden.

Raf MERTENS

Algemeen Directeur

SAMENVATTING

ACHTERGROND EN DOEL

In een sociaal systeem voor ziekteverzekering moeten beleidsbeslissingen inzake gezondheidszorg de sociale waarden weerspiegelen. Op macroniveau moeten prioriteiten worden gesteld voor de toewijzing van de middelen voor de gezondheidszorg, op meso-niveau moeten beslissingen genomen worden met betrekking tot de terugbetaling van producten en diensten voor een bepaalde ziekte en op microniveau moeten er beslissingen genomen worden met betrekking tot de terugbetaling voor een bepaalde patiënt. Vandaag wordt in België van de verkozen politici verwacht dat ze het grote publiek vertegenwoordigen bij het bepalen van de globale prioriteiten voor de gezondheidszorg. Voor de terugbetaling van producten en diensten wordt in het huidige systeem overleg gepleegd tussen de verschillende belanghebbenden. Patiënten en burgers nemen niet deel aan dit debat. Sommige deelnemende belanghebbenden beweren dat ze de patiënten en burgers vertegenwoordigen, maar het blijft onduidelijk hoe ze dit doen, omdat er geen gestructureerde raadpleging met de patiënten en burgers plaatsvindt.

De doelstellingen van deze studie zijn (1) mogelijke modellen te beschrijven voor het betrekken van het publiek en de patiënten in de besluitvorming inzake gezondheidszorg op verschillende niveaus en (2) de aanvaardbaarheid van deze modellen voor de Belgische belanghebbenden te beoordelen.

METHODES

Er werd een uitgebreid, maar niet systematisch literatuuronderzoek uitgevoerd om de kenmerken van betrokkenheid van de burger en de patiënt te beschrijven. Op basis van deze beoordeling werd een kader ontwikkeld om modellen te beschrijven voor het betrekken van het publiek en de patiënt bij beslissingsprocessen.

De aanvaardbaarheid van verschillende modellen en modaliteiten voor de betrokkenheid van het publiek en de patiënt in België werd geëvalueerd aan de hand van een Delphi-onderzoek met 2 rondes onder een brede waaier van belanghebbenden die op dit moment al dan (nog) niet betrokken zijn bij de besluitvormingsprocessen. Er werden drie soorten beslissingen in overweging genomen: strategische (macro), operationele

(meso) en individuele (micro) beslissingen. Tachtig belanghebbenden namen deel aan beide Delphi-rondes. Consensus werd gedefinieerd als ≥ 65% van de respondenten die het eens was met een uitspraak.

RESULTATEN

Literatuur

Er is in de literatuur weinig onderzoek gedaan naar welk model van betrokkenheid van het publiek en de patiënt het meest efficiënt is in welke omstandigheden. Betrokkenheid heeft meerdere dimensies, die te maken hebben met de intensiteit, plaats, timing, techniek en gevolgen van de betrokkenheid.

Intensiteit verwijst naar de mate waarin burgers en patiënten controle hebben over het besluitvormingsproces. Betrokkenheid kan zijn, in oplopende volgorde van intensiteit: informeren, raadplegen, debatteren, mee beslissen, en het publiek of de patiënt laten beslissen.

De betrokkenheid kan plaatsvinden binnen of buiten de huidige besluitvormingsorganen; bij alle beraadslagingen, op specifieke mijlpalen of aan het einde van het besluitvormingsproces; vlak voordat of nadat een beslissing wordt genomen; met slechts één of met meerdere vertegenwoordiger(s); met een vaste of een veranderende vertegenwoordiging; met schriftelijke en/of mondelinge bijdrage; mits fysieke aanwezigheid of van op afstand. Volgens de literatuur is de beste manier om het publiek te betrekken bij het vooropstellen van prioriteiten om meerdere participatiemethoden te gebruiken, meerdere vertegenwoordigers erbij te betrekken, en methoden te gebruiken op verschillende niveaus van intensiteit om een meer gedifferentieerd begrip te krijgen van de waarden van het publiek en de patiënten. Een mogelijke bedreiging voor het succes van de betrokkenheid van het publiek en de patiënt is het gebrek aan evenwicht tussen de invloeden van de betrokken partijen.

Empirische literatuur laat zien dat burgers of patiënten misschien niet betrokken willen worden bij of geen verantwoordelijkheid willen delen voor de besluitvorming, of dat hun verlangen om betrokken te worden bij beslissingen in verband met gezondheidszorg kan verschillen. Er lijkt een sterker verlangen te bestaan om te worden betrokken op het systeem- en programmaniveau dan op het individuele patiëntniveau.

Delphi-panel

De deelnemers aan het Delphi-panel waren het erover eens dat betrokkenheid van burgers en patiënten in de besluitvorming inzake gezondheidszorg belangrijk is op zowel het strategisch als het operationeel niveau. Aan de ene kant zou dit het publiek en de patiënten bewuster kunnen maken van de uitdagingen en kosten van de gezondheidszorg. Aan de andere kant zou betrokkenheid van patiënten in het bijzonder de besluitvormingsprocessen kunnen verrijken met expertise door ervaring van patiënten. Daarom zou er een rol weggelegd zijn voor een vertegenwoordiger van de burger voor beslissingen over de prioriteiten voor het gebruik van middelen in de gezondheidszorg en voor een vertegenwoordiger van de patiënt voor beslissingen over de terugbetaling van producten en diensten.

Volgens het Delphi-panel was er geen eenduidige rationale voor het betrekken van het publiek en de patiënt in het besluitvormingsproces: zowel consequentalistische als democratische, empowerment of individualistische/bekwaam-makende redenen werden beschouwd als gerechtvaardigde gronden om het publiek en de patiënt te betrekken in het gezondheidszorgbeleid.

Het model voor publieke- en patiëntenbetrokkenheid dat de voorkeur genoot was: het publiek en de patiënten raadplegen binnen de bestaande besluitvormingsorganen en op specifieke mijlpalen in het besluitvormingsproces. Meer dan één vertegenwoordiger van het publiek en de patiënten kreeg de voorkeur boven slechts één vertegenwoordiger, en veranderende vertegenwoordigers kregen de voorkeur boven een vaste vertegenwoordiging van de burgers en patiënten. Tenslotte vond men dat beslissingen moeten worden gemotiveerd wanneer ze afwijken van het advies van de vertegenwoordigers van het publiek en de patiënten.

Het panel identificeerde verschillende risicofactoren voor het succes van het betrekken van het publiek en de patiënt bij de besluitvorming. Toch was men het er over eens dat de voordelen opwegen tegen de risico's. Opleiding van alle belanghebbenden, transparantie van het besluitvormingsproces, erkenning en financiering van

patiëntenorganisaties, en de ontwikkeling van een participatiecultuur werden beschouwd als cruciaal voor het succes van de betrokkenheid.

Ziekenfondsen werden beschouwd als de belanghebbenden die de burgers en patiënten vandaag de facto vertegenwoordigen in de beslissingsorganen. In een ideale wereld is er volgens de deelnemers echter een meer prominente rol weggelegd voor patiëntenorganisaties dan nu het geval is. Ziekenfondsen en patiëntenorganisaties kunnen als complementair worden beschouwd.

DISCUSSIE EN CONCLUSIE

Er bestaat een consensus over het belang van de betrokkenheid van het publiek en de patiënt en over een positieve baten/risicoverhouding. Volgens de deelnemers aan het Delphi-onderzoek moet dit echter wel gebeuren binnen de huidige besluitvormingsstructuren. Dit kan worden verklaard door het profiel van de respondenten (66% heeft momenteel ervaring met de besluitvormende organen) en een gebrek aan ervaring met participatie.

Het publiek en patiënten betrekken bij de besluitvorming is een sociaal proces, geen discrete interventie. Het vereist een voortdurend engagement van alle belanghebbenden om wederzijds vertrouwen en een zinvolle communicatie op te bouwen. Daarom moet elk initiatief om het publiek en de patiënt te betrekken de efficiëntie ervan beoordelen op het vlak van processen en resultaten. Procesindicatoren hebben betrekking op vertegenwoordiging, procedureregels en informatie; resultaatindicatoren hebben betrekking op de kwaliteit van de beslissingen, waarbij kwaliteit kan worden gedefinieerd als de mate waarin de beslissingen stroken met de sociale waarden. Bijkomende informatie over deze sociale waarden kan hiervoor nodig zijn. Bovendien is er door het huidige gebrek aan bewijs over de efficiëntie van modellen voor de betrokkenheid van het publiek en de patiënt in de besluitvorming in verschillende contexten en verschillende gezondheidszorgstelsels met verschillende besluitvormingsprocedures, dringend behoefte aan meer vergelijkend onderzoek over dit onderwerp.

AANBEVELINGEN[a]

Aan al wie betrokken is bij de besluitvorming in de gezondheidszorg, op nationaal, regionaal en lokaal niveau en de Koning Boudewijnstichting :

Een proces opstarten om een expliciete burger- en patiëntenparticipatiecultuur te creëren binnen de besluitvormingsorganen. Dit zou kunnen door middel van bewustmakings-campagnes, via een specifiek actieplan met doelstellingen, activiteiten en monitoring en door middel van proefprojecten.

Bij het selecteren van de proefprojecten:

- **Zich concentreren op onderwerpen waarvoor de consensus mbt het belang van burger- en patiëntenbetrokkenheid het grootst was, namelijk invasieve medische apparatuur en dure of veelgebruikte geneesmiddelen.**
- **Toepassen van "overleg" of "deelname aan debat" in verschillende projecten, om de grenzen van beide niveaus van intensiteit af te tasten.**
- **Wat betreft het beslissingsniveau en wie betrokken moet worden:**
  - **wanneer het gaat om het stellen van prioriteiten voor het gebruik van schaarse middelen in de gezondheidszorg: bij voorkeur vertegenwoordiging van de burgers;**
  - **wanneer het gaat om beslissingen over terugbetaling van nieuwe producten of diensten en men beroep wil doen op ervaringsdeskundigen: patiënten-vertegenwoordiging;**
  - **in andere situaties: patiënten of burgers of een combinatie ervan.**
- **Naast het testen van betrokkenheid binnen de bestaande organen, ook experimenteren met betrokkenheid buiten deze organen, inclusief met betrokkenheid georganiseerd via het kanaal van de ziekenfondsen.**

Voor de implementatie van de proefprojecten:

- **Investeren in capaciteitsopbouw van alle betrokken actoren om ervoor te zorgen dat de succesvoorwaarden vervuld zijn.**

Voor de evaluatie van de proefprojecten:

- **Proefprojecten behandelen als onderzoeksprojecten met ingebouwde monitoring en evaluatie waarin zowel het proces als de resultaten en de risico's en succesfactoren aan bod komen.**

[a] Alleen het KCE is verantwoordelijk voor de aanbevelingen aan de overheid

Aan de ziekenfondsen, patiëntenorganisaties, zorgverstrekkers en zorginstellingen:

- **Actief deelnemen aan de hierboven voorgestelde proefprojecten.**

Aan de ziekenfondsen:

- **De ziekenfondsen zouden de patiënten kunnen vertegenwoordigen via een gestructureerde mobilisering van de voorkeuren en kennis van hun leden en/of door samenwerking met patiëntenorganisaties.**

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
IAP2	International Association for Public Participation
KBF – KBS – FRB	King Baudouin Foundation – Koning Boudewijn Stichting – Fondation Roi Baudouin
KCE	Belgian Health Care Knowledge Centre – Federaal Kenniscentrum voor de Gezondheidszorg – Centre Fédéral d'Expertise des Soins de Santé
RIZIV – INAMI – NIHDI	Rijksinstituut voor Ziekte- en Invaliditeitsverzekering – Institut National d'Assurance Maladie-Invalidité – National Institute for Health and Disability Insurance
VAT	Value-added tax
WHO	World Health Organisation

SYNTHESE

1. ACHTERGROND

In een systeem van sociale ziekteverzekering moeten beleidsbeslissingen inzake gezondheidszorg de maatschappelijke waarden weerspiegelen. Maatschappelijke waarden zijn principes die waardevol of belangrijk worden geacht door de leden van een samenleving.

Burgers en patiënten betrekken bij de besluitvorming is één manier om dit doel te proberen te bereiken. Maatschappelijke evoluties zoals hogere opleidingsniveaus, hogere verwachtingen van de patiënt ten aanzien van de kwaliteit en kwantiteit van gezondheidszorg, en financiële beperkingen, worden geassocieerd met de toenemende populariteit van burger- en patiëntenparticipatie. De betrokkenheid van burgers en patiënten past met name binnen een context waarin het legitimeren van beleidsbeslissingen inzake gezondheidszorg steeds belangrijker wordt.

De betrokkenheid van burgers en patiënten is contextgebonden. Deze context omvat de politieke, maatschappelijke en organisatorische omgeving waarin de betrokkenheid wordt georganiseerd, maar ook de onderliggende motivering, het doel van de betrokkenheid en de kenmerken van het besluitvormingsproces.

In België wordt vandaag een deliberatie-gedreven model van besluitvorming gehanteerd waarbij verschillende belanghebbenden (met name wetenschappers, ziekenfondsen, vertegenwoordigers uit de farmaceutische industrie, vertegenwoordigers uit de medische en zorginstellingen en politici) in een beoordelingscommissie zetelen. Er wordt verondersteld dat op door deze vertegenwoordiging van diverse belangengroepen beleidsbeslissingen de maatschappelijk waarden zullen weerspiegelen, zonder patiënten of burgers rechtstreeks te betrekken bij het besluitvormingsproces. De belangen van burgers en patiënten worden verondersteld te worden verdedigd door de belanghebbenden die op dit moment reeds betrokken zijn bij het besluitvormingsproces.[a]

[a] Sommige stakeholders, in casu de ziekenfondsen, organiseren reeds consultatierondes met burgers en patiënten, met als doel de publieke opinie over een bepaalde problematiek of thematiek te achterhalen.

Het blijft echter onduidelijk hoe de maatschappelijke waarden precies worden meegenomen in terugbetalingsbeslissingen voor specifieke producten of diensten, in afwezigheid van een gestructureerde raadpleging of gestructureerd overleg met de burgers en patiënten voor dergelijke concrete beslissingen. Er werd nog maar weinig onderzoek verricht naar welk model voor het betrekken van burgers en patiënten het meest effectief is in welke omstandigheden.

2. DOELSTELLINGEN EN ALGEMENE OPZET VAN DE STUDIE

De voornaamste doelstelling van deze studie is te evalueren wat de toegevoegde waarde kan zijn van het betrekken van burgers en patiënten in het gezondheidszorgbeleid in België, vergeleken met de huidige situatie waar reeds bepaalde inspanningen worden gedaan om patiënten en burgers te betrekken in het besluitvormingsproces, zij het op een eerder indirecte manier.

De studie beschrijft verschillende modellen om het publiek en de patiënt te betrekken bij de besluitvorming inzake gezondheidszorg en beoordeelt de aanvaardbaarheid ervan in België. Aanvankelijk ging onze aandacht vooral uit naar beslissingen over de terugbetaling van producten. Uit het literatuuroverzicht leerden we echter dat betrokkenheid van burgers en patiënten ook relevant is voor ruimere, strategische beleidskwesties, zoals het bepalen van prioriteiten voor de toewijzing van middelen in de gezondheidszorg. Bovendien moeten terugbetalingsbeslissingen voor concrete producten of diensten in principe dezelfde waarden weerspiegelen als diegene die gelden op strategisch niveau. Daarom werd de aanvaardbaarheid van modellen voor strategische beslissingen ook opgenomen in onze beoordeling.

De aanvaardbaarheid van verschillende modellen en de voorwaarden om burgers en patiënten te betrekken bij dergelijke besluitvormingsprocessen in de Belgische context werd beoordeeld aan de hand van een Delphi-onderzoek in 2 rondes bij Belgische stakeholders (belanghebbenden) die momenteel betrokken zijn of (nog) niet betrokken zijn bij de besluitvorming. Een breed scala van stakeholders werd uitgenodigd om deel te nemen aan het onderzoek, waaronder politici, hooggeplaatste ambtenaren en beleidsmakers op nationaal, regionaal en lokaal niveau, alle leden van de beslissingsorganen bij het RIZIV, consumenten- en patiëntenverenigingen. Alle stakeholders waren vertegenwoordigd in de 107 deelnemers aan de eerste ronde van het Delphi-panel. Aan de deelnemers werd gevraagd om hun persoonlijke mening en niet de mening van hun organisatie te geven. Uiteindelijk namen 80 personen deel aan beide Delphi-rondes.

3. MOGELIJKE MODELLEN VOOR HET BETREKKEN VAN BURGERS EN PATIËNTEN EN DE AANVAARDBAARHEID ERVAN IN BELGIË

3.1. Belang, motivering en voordelen van het betrekken van burgers en patiënten in het algemeen

3.1.1. Belang

Over het algemeen was men het er in grote mate over eens dat het belangrijk is om burgers en patiënten te betrekken bij de besluitvorming inzake gezondheidszorg. De kleine minderheid van respondenten die het niet belangrijk vond om burgers en patiënten te betrekken (8%), is afkomstig van diverse categorieën van stakeholders.

3.1.2. Motivering voor betrokkenheid van publiek en patiënten

Er waren volgens het Delphi-panel verschillende redenen om burgers en patiënten te betrekken, zonder één doorslaggevende reden. De rationales hadden betrekking op de verschillende potentiële beweegredenen om burgers en patiënten te betrekken zoals die ook in de literatuur worden beschreven:

- het consequentalistische technocratische of consumentenperspectief, waarbij het betrekken van burgers en patiënten kan worden beschouwd als een middel om beleidsdoelen zoals efficiëntie, toegankelijkheid en kwaliteit van zorg te bereiken;
- de empowerment, het emanciperende of democratische perspectief, waarbij de betrokkenheid van burgers en patiënten een doel op zich is, met meer nadruk op het fundamentele recht van burgers om deel te nemen aan besluitvormingsprocessen;
- het individualistische, bekwaammakende perspectief, waarbij de betrokkenheid van burgers en patiënten een instrument is dat de bevolking de kans geeft om de verantwoordelijkheid op te nemen voor haar eigen keuzes.

3.1.3. Voordelen van betrokkenheid van publiek en patiënten

Volgens de respondenten heeft het betrekken van burgers en patiënten in het beslissingsproces twee belangrijke voordelen. Een voordeel van patiëntenparticipatie bestaat erin dat beoordelaars in het besluitvormingsproces omtrent terugbetaling van producten of diensten een beter begrip kunnen verwerven van alles wat betrekking heeft op de levenskwaliteit van patiënten en de moeilijkheden waarmee patiënten geconfronteerd worden. Een voordeel van burgerparticipatie is een groter publiek bewustzijn van de uitdagingen, kosten en opportuniteitskosten van gezondheidszorg, wat mogelijks kan leiden tot meer individuele en collectieve verantwoordelijkheid.

3.2. Kenmerken van scenario's voor burger- en patiëntenparticipatie

Ten behoeve van de studie ontwikkelden we een kader om mogelijke scenario's te beschrijven voor de het betrekken van burgers en patiënten in besluitvormingsprocessen op basis van een uitgebreide literatuurstudie en de bestaande nationale besluitvormingsstructuren voor terugbetalingen in de gezondheidszorg in België. De verschillende dimensies van het kader zijn het **voorwerp van de beslissing,** de **keuze van de vertegenwoordiger** van burgers en patiënten voor elk type besluit, de **intensiteit** van burger- en patiëntenparticipatie, en de **participatiemethode.**

3.2.1. Voor welke beslissingen kan burger- en patiëntenparticipatie overwogen worden?

Maatschappelijke waarden, en bijgevolg burger- en patiëntenparticipatie, zijn relevant op verschillende besluitvormingsniveaus: op strategisch niveau gaat het over de keuzes met betrekking tot de verdeling van de financiële middelen; op het operationele niveau gaat het over beslissingen over terugbetaling van producten en diensten. Met betrekking tot het operationele niveau, bereikte het Delphi-panel een consensus dat patiëntenparticipatie belangrijk is voor diverse types terugbetalingsbeslissingen, zoals beslissingen aangaande geneesmiddelen met hoge kostprijs, geneesmiddelen met groot verbruiksvolume, nieuwe diagnostische technieken en invasieve medische hulpmiddelen. Ook voor beslissingen over de terugbetaling van producten

en therapieën die vandaag ten laste zijn van de patiënt, werd patiëntenparticipatie weerhouden als relevant. Er werd geen consensus bereikt over de relevantie van burger- en patiëntenparticipatie voor beslissingen aangaande dure geneesmiddelen met een beperkte therapeutische meerwaarde.

3.2.2. Wie vertegenwoordigt de burgers en de patiënten?

In het concept van burger- en patiëntenparticipatie worden burgers en patiënten gedefinieerd als rollen of personen binnen het besluitvormingsproces. Behalve voor patiënten die optreden als ervaringsdeskundigen, staat de rol van de burgers en patiënten in de besluitvormingsprocessen los van de bijzondere status van deze persoon. In dit rapport maken we een onderscheid tussen (1) de vertegenwoordigers van burgers die de rol spelen van de belastingbetaler, (2) vertegenwoordigers van patiënten, die de dubbele rol spelen van de (potentiële) patiënt en de consument van de gezondheidszorg en (3) patiënten als ervaringsdeskundigen.

Het Delphi-panel oordeelde dat het betrekken van burgers het meest aangewezen is voor strategische beslissingen (het stellen van budgettaire prioriteiten). Voor operationele beslissingen daarentegen, is de patiënt beter geplaatst.

3.2.3. Intensiteit van de participatie van het publiek en de patiënt

De intensiteit van de participatie is "*de mate waarin individuen controle hebben over het besluitvormingsproces*" (Charles en DeMaio, 1993[1] p. 893). Er werd een brede waaier van participatieniveaus gedocumenteerd in de literatuur. Voor de intensiteit van burger- en patiëntenparticipatie werd het spectrum van de International Association for Public Participation (Internationale Vereniging voor Publieksparticipatie (IAP2) gebruikt in deze studie. Op het meest rudimentaire niveau wordt de vertegenwoordiger van de burgers en patiënten louter ingelicht, wat betekent dat hij geen macht toegekend krijgt. De hoogste graad van machtsoverdracht vindt plaats wanneer beslissingen eigenlijk worden genomen door het publiek. Consulteren, deelname aan het debat en medebeslissing zijn tussenliggende niveaus van betrokkenheid, met een oplopende graad van machtsoverdracht.

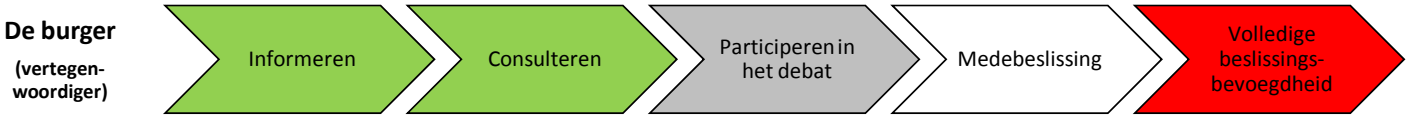
Het geprefereerde en het minimale niveau van intensiteit van burger- en patiëntenparticipatie dat de voorkeur genoot en de rol van de vertegenwoordiger, hingen af van de aard van de beslissing. In het Delphi-panel werd een consensus bereikt over de volgende aspecten (Afbeelding i):

- om globale budgettaire prioriteiten op te stellen in de gezondheidszorg, zouden de vertegenwoordigers van de burger op zijn minst moeten worden geïnformeerd en geconsulteerd;
- voor beslissingen over de terugbetaling van specifieke producten zouden de vertegenwoordigers van de patiënten op zijn minst moeten worden geïnformeerd en geconsulteerd;
- voor beslissingen met betrekking tot de terugbetaling van producten voor een individuele patiënt bestond er geen consensus over de vraag of burgers of patiënten er überhaupt bij betrokken moeten worden.

Hoewel men het erover eens was dat consulteren het minimale participatieniveau moet zijn voor zowel de keuze van algemene prioriteiten als voor specifieke beslissingen over terugbetaling, bestond er geen consensus over wat het maximale betrokkenheidniveau moet zijn. Ongeveer 24% van de deelnemers was uitdrukkelijk gekant tegen de deelname door burgers in het debat over de prioriteiten inzake gezondheidszorg, en 25% was tegen de deelname van burgers of patiënten aan het debat voor beslissingen over de terugbetaling van producten en diensten. De rest, d.w.z. respectievelijk 76% en 75%, vond deelname aan het debat een aanvaardbaar niveau van betrokkenheid, hoewel het voor sommigen niet de voorkeur genoot. Volledige beslissingsbevoegdheid voor burgers en patiënten werd expliciet verworpen als optie voor elk type van besluitvorming.

Afbeelding i - Aanvaardbare en niet-aanvaardbare niveaus van burger- en patiëntenparticipatie

1. Om globale prioriteiten voor het gebruik van de beschikbare middelen voorop te stellen



2. Om te beslissen over de terugbetaling van prestaties gekoppeld aan een specifieke ziekte of behandeling



3. Om te beslissen over de terugbetaling voor een individuele patiënt



Groen: consensus over aanvaarding als minimaal betrokkenheidniveau
Grijs: aanvaardbaar betrokkenheidniveau, maar geen consensus over de vraag of dit het minimum- of maximumniveau moet zijn. Wit: geen consensus
Rood: consensus over verwerping

3.2.4. Scenario's van burger- en patiëntenparticipatie

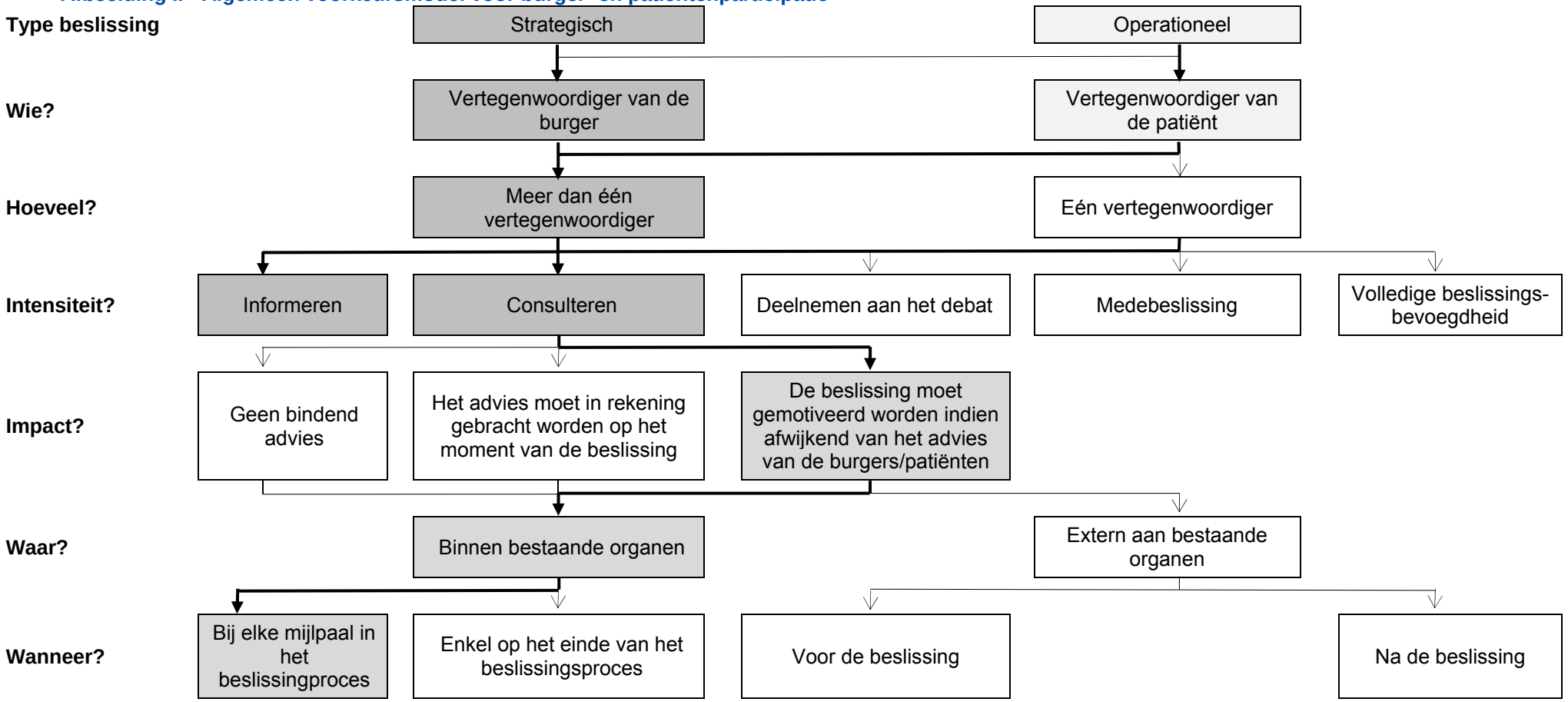
Er zijn verschillende scenario's mogelijk voor het informeren of consulteren van burgers of patiënten. Ons beschrijvend kader voor de scenario's definieert verschillende dimensies waarover beslissingen moeten worden genomen:

- **waar** de betrokkenheid plaatsvindt (binnen de huidige besluitvormingsorganen (bijv. expertencommissies) of buiten de bestaande organen (bijv. in een specifiek daartoe opgericht adviesorgaan);
- **wanneer** burgers en patiënten betrokken moeten worden (bij alle beraadslagingen, alleen op mijlpaalpunten tijdens de besluitvorming, pas aan het einde van het proces, of alleen vlak voor of na de beslissing);
- **hoe** de betrokkenheid georganiseerd moet worden (met slechts één vertegenwoordiger of met meer dan één vertegenwoordiger, een vaste of een veranderende vertegenwoordiging, met schriftelijke en/of mondelinge bijdrage, met fysieke aanwezigheid of van op afstand).

Daarnaast werd een vraag gesteld over de impact die de participatie moet hebben in het geval van consultatie, d.w.z. of het advies bindend of niet-bindend moet zijn, en als het niet bindend is, of eventuele afwijkingen van het advies van de burgers en patiënten moeten worden gemotiveerd. Er werd een afzonderlijk scenario voorgesteld voor de twee betrokkenheidniveaus die werden geïdentificeerd als minimaal vereist voor elk type van beslissing (cfr. Afbeelding i).

Het voorkeursscenario om burgers en patiënten bij de besluitvorming te betrekken, was volgens ons Delphi-panel dat het publiek en de patiënten geconsulteerd moeten worden binnen de bestaande besluitvormingsorganen en op specifieke mijlpaalpunten in het besluitvormingsproces. Er wordt voorkeur gegeven aan meer dan één vertegenwoordiger van burgers en patiënten in plaats van slechts één vertegenwoordiger. Wijzigende vertegenwoordigers kregen de voorkeur boven een vaste vertegenwoordiging. Beslissingen moeten gemotiveerd worden wanneer ze afwijken van het advies van de vertegenwoordigers van de burgers en patiënten (Afbeelding ii).

Afbeelding II - Algemeen voorkeursmodel voor burger- en patiëntenparticipatie



3.3. Risico's van burger- en patiëntenparticipatie

Ook al was er geen consensus over welk scenario voor burger- en patiëntenparticipatie in het besluitvormingsproces de voorkeur geniet, toch werden een aantal mogelijke risico's die in de literatuur werden beschreven ook gedeeld door de deelnemers aan het Delphi-panel.

Volgens de literatuur gaat het betrekken van burgers en patiënten over de verdeling van macht tussen de belanghebbenden in het gezondheidszorgbeleid. Het gebrek aan evenwicht tussen de bevoegdheden werd omschreven als een potentieel risico voor burger- en patiëntenparticipatie in de besluitvormingsprocessen. Het Delphi-panel identificeerde de volgende risico's en problemen in verband met burger- en patiëntenparticipatie: 1) gebrek aan menselijke en financiële middelen van burgers en patiënten om effectief te participeren, 2) de moeilijkheid een gepaste vertegenwoordiging te vinden om een collectieve mening te uiten, 3) het risico voor patiënten om te worden geïnstrumentaliseerd, en 4) de lobby of machtspelletjes van andere stakeholders. Daarnaast bestaat er een gepercipieerd risico van subjectiviteit. Er was eensgezindheid over het feit dat er geen risico bestaat dat zeldzame ziekten minder aandacht zouden krijgen als gevolg van de betrokkenheid van burgers en patiënten.

Ondanks de geïdentificeerde risico's waren de deelnemers het erover eens dat de voordelen van betrokkenheid van burgers en patiënten opwegen tegen de risico's.

3.4. Succesfactoren

Het Delphi-panel bereikte een consensus over de volgende succesfactoren: 1) het opleiden van burgers en patiënten en andere stakeholders om effectief te kunnen bijdragen aan de besluitvorming, 2) transparantie van het besluitvormingsproces, 3) formele erkenning en financiering van patiëntenorganisaties, en 4) de ontwikkeling van een participatiecultuur en gedragscode voor de deelnemende personen en verenigingen. De respondenten waren het er ook over eens dat er een juridische basis moet ontwikkeld worden voor burger en patiëntenparticipatie. Tot slot is de behoefte algemeen aanwezig om de personen die zouden participeren, zorgvuldig te selecteren.

3.5. Wie vertegenwoordigt de burgers en patiënten en WIE zou ze moeten vertegenwoordigen?

We vroegen ons Delphi-panel wie momenteel de burgers en patiënten vertegenwoordigt en wie hen het best zou vertegenwoordigen voor drie soorten beslissingen: 1) prioriteiten voor de toewijzing van middelen, 2) terugbetaling van producten en 3) terugbetaling voor individuele patiënten.

3.5.1. Vandaag: het belang van de ziekenfondsen

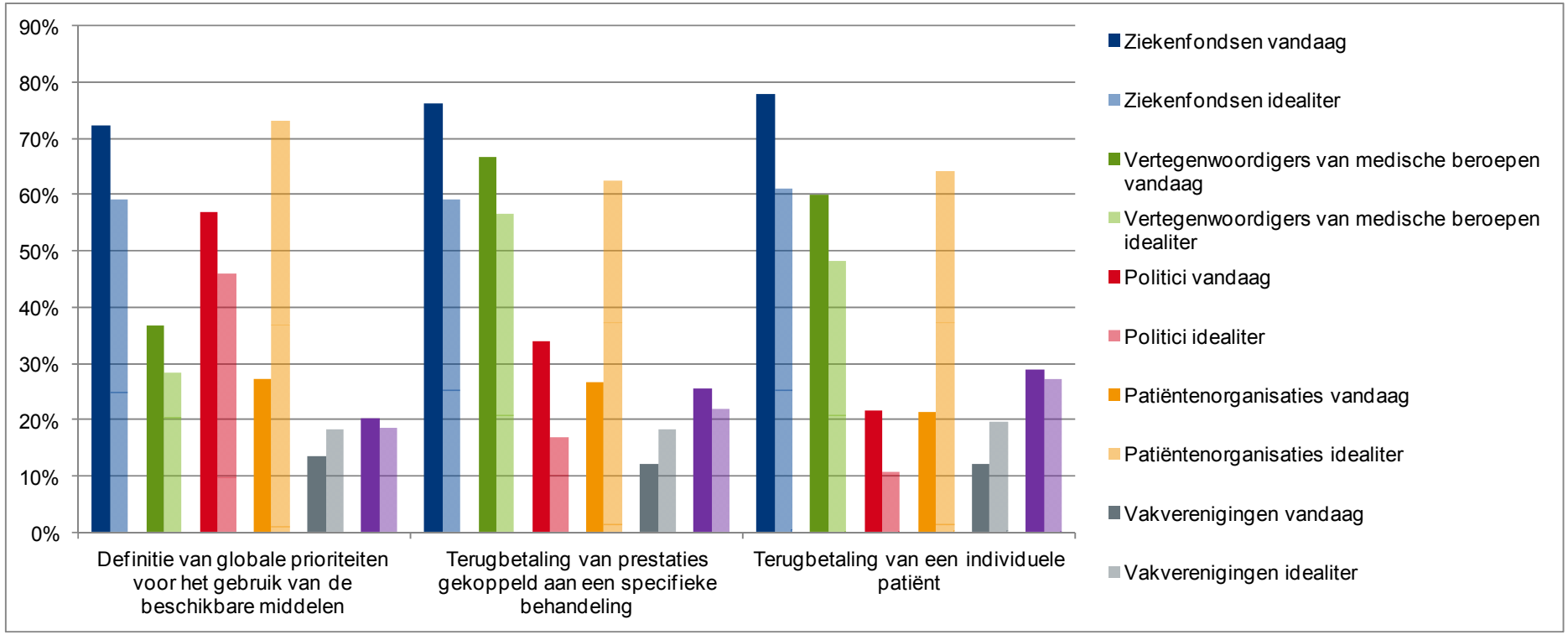
Volgens de meerderheid van de bevraagden worden burgers en patiënten momenteel vertegenwoordigd door de ziekenfondsen in besluitvormingsprocessen met betrekking tot prioriteiten in de toewijzing van middelen in de gezondheidszorg, terugbetaling van producten en terugbetaling voor individuele patiënten. Meer dan 50% van de respondenten plaatste de ziekenfondsen bovenaan als de huidige vertegenwoordigers van burgers en patiënten voor deze drie soorten beslissingen. Meer dan 70% zette ze in de top drie van de huidige vertegenwoordigers.

3.5.2. Morgen: meer ruimte voor patiëntenorganisaties en vakverenigingen?

De vergelijking tussen de gepercipieerde huidige vertegenwoordiger en de "ideale" vertegenwoordiger suggereert dat de rol van de ziekenfondsen als vertegenwoordigers van de burgers en patiënten niet in vraag wordt gesteld door de belanghebbenden. Afbeelding iii toont de top drie van de beste vertegenwoordigers van burgers en patiënten voor elk type beslissing volgens de respondenten, met uitzondering van respondenten die naar zichzelf verwezen hebben. Wanneer de stakeholders die kozen voor hun eigen stakeholder groep werden meegenomen in de analyse, stegen de percentages voor alle stakeholder groepen, maar de rangorde veranderde niet. Het gevoel bestaat echter dat patiëntenorganisaties en de vakverenigingen explicieter aanwezig zouden moeten zijn dan nu. De grootste veranderingen hadden betrekking op de patiëntenorganisaties. De resultaten weergegeven in de figuur moeten met de nodige voorzichtigheid worden geïnterpreteerd, omdat een bestaande (gekende) situatie vergeleken wordt met een mogelijke (onbekende) situatie. Gezien de prominente rol van de ziekenfondsen in de huidige besluitvormingsprocessen, hebben de meeste belanghebbenden ervaring

met de voordelen en beperkingen ervan. De gevolgen van een participatie van patiëntenorganisaties zijn onzeker, omdat de ervaring beperkt of onbestaande is. Ondanks het gebrek aan ervaring met burger- en patiëntenparticipatie verwachten de belanghebbenden dat de ervaringen positief zullen zijn.

Afbeelding iii - Wie staat er vandaag in de top 3 van de burger- en patiëntenvertegenwoordigers in vergelijking met de ideale situatie in België per type beslissing (exclusief zelf-verwijzingen)



4. EVALUATIE VAN INITIATIEVEN OM BURGERS EN PATIËNTEN TE BETREKKEN BIJ DE BESLUITVORMING

Wanneer er besloten wordt om burgers en patiënten te betrekken bij de besluitvorming inzake gezondheidszorg, zou moeten nagegaan worden in hoeverre de vooropgestelde doelstellingen werden bereikt. Zowel het proces als de resultaten moeten geëvalueerd worden. Procesindicatoren hebben betrekking op vertegenwoordiging, procedureregels en informatie, terwijl resultaatindicatoren betrekking hebben op de kwaliteit van de beslissingen, het vertrouwen van het publiek in het goed functioneren van het gezondheidszorgsysteem en het gevoel gehoord te worden, maar ook mogelijke onverwachte effecten, zoals het gevoel gebruikt te worden door andere stakeholders. Voor elke indicator zijn er verschillende definities mogelijk. De vertegenwoordiging zou bijvoorbeeld betrekking kunnen hebben op geografische, demografische of politieke vertegenwoordiging, maar ook op de vertegenwoordiging van discursieve standpunten in de samenleving.

Momenteel is er een gebrek aan bewijs met betrekking tot de doeltreffendheid van de modellen om burgers en patiënten te betrekken in verschillende contexten die relevant zijn voor de verschillende gezondheidszorgsystemen met verschillende soorten besluitvormingsprocedures. Gebaseerd op de waarden gedefinieerd door IAP2 zouden er procesindicatoren voor initiatieven waarin burgers en patiënten betrokken worden, kunnen gedefinieerd worden voor latere evaluatie. Resultaatsindicatoren zouden kunnen ontwikkeld worden gebaseerd op transparante criteria voor besluitvorming, waarvan de relatieve waarde moet afgetoetst worden bij het algemene publiek. Dit zijn denkpistes voor toekomstig onderzoek.

5. DISCUSSIE

Voor zover we weten is dit de eerste studie die aanvaardbaarheid van burger- en patiëntenparticipatie in beleidsbeslissingen aangaande gezondheidszorg onderzoekt. De voornaamste sterktes zijn het betrekken van verschillende types van stakeholders in het Delphi panel, de differentiatie tussen types van beslissingen en het interpreteren van de resultaten in de Belgische context. Het belang en de potentiële impact van de resultaten is niet te onderschatten. Stakeholders prefereerden een veeleisend scenario van burger- en patiëntenparticipatie voor zowel strategische als operationele beslissingen.

Onze studie heeft een aantal beperkingen. Ten eerste gebruikten we de intensiteitsladder van de IAP2 als uitgangspunt, zonder de verschillende graden van intensiteit in vraag te stellen. Een aantal auteurs heeft echter kritiek geuit op deze hiërarchische benadering van burger- en patiëntenparticipatie. Bijvoorbeeld Litva et al. (2002) laten zien dat de intensiteit van de betrokkenheid van mensen uit het publiek bij voorkeur ligt tussen consultatie en "betrokkenheid", waarbij betrokkenheid wordt gedefinieerd als een soort van partnerschap waarbij de verantwoordelijkheid voor de besluitvorming wordt gedeeld tussen professionals en het publiek.[2] Consultatie verwijst naar "*een mogelijkheid voor individuen om hun mening te uiten, maar het biedt geen garantie dat er rekening wordt gehouden met de individuele standpunten*" (Charles en DeMaio, 1993[1], geciteerd door Litva et al., 2002). Litva et al. (2002) komen tot de conclusie dat er een grote kloof bestaat tussen deze graden van betrokkenheid. De deelnemers aan de studie van Litva et al. (2002) wilden hun betrokkenheid net situeren in deze kloof.[2]

In onze Delphi-enquête hebben we geen rekening gehouden met de mogelijkheid van "verantwoordelijke raadpleging", d.w.z. de bijdrage aan beslissingen door meningen te uiten met de garantie dat deze bijdrage wordt in rekening gebracht, zonder verantwoordelijkheid voor de beslissing, maar met het oog op de motivering van de beslissing die uiteindelijk wordt gemaakt. In de tweede Delphi-ronde kregen de deelnemers bij de scenario's echter wel de kans om hun voorkeur te laten blijken inzake de impact van het burger- en patiëntenadvies op de besluitvorming. Zowel bij het bepalen van de globale prioriteiten als bij

beslissingen in verband met specifieke behandelingen, gaf de meerderheid van de respondenten de voorkeur aan het moeten motiveren van een beslissing die afwijkt van het advies van burgers en patiënten. Ten tweede hebben we geen individuele burgers of patiënten opgenomen in ons Delphi-panel. Hun standpunt is dus slechts gedeeltelijk opgenomen in deze studie, via de stem van de patiëntenorganisaties. Eerder onderzoek heeft aangetoond dat in sommige situaties bepaalde burgers of patiënten niet betrokken willen worden en niet willen delen in de verantwoordelijkheid. Dit lijkt van toepassing te zijn op beslissingen op het niveau van de individuele patiënt. Burgers willen echter wel betrokken worden op systeemniveau.

Ten slotte moet deze studie worden beschouwd als een eerste stap in een langer proces van burger- en patiëntenparticipatie. We hebben de 'aanvaardbaarheid' van burger- en patiëntenparticipatie getest en de voorwaarden voor een mogelijke implementatie onderzocht. De volgende stappen zouden zijn om de daadwerkelijke implementatie uit te proberen en een dergelijk proces van burger- en patiëntenparticipatie te evalueren. Burger- en patiëntenparticipatie is slechts één manier om publieke waarden en voorkeuren te introduceren in het besluitvormingsproces. Aanvullende benaderingen zouden bijvoorbeeld kunnen bestaan uit het wetenschappelijk en bij voorkeur herhaaldelijk meten van de waarden van het publiek en de voorkeuren voor de prioriteitsbepaling binnen de gezondheidszorg, en deze informatie te gebruiken in de werkelijke besluitvormingsprocessen als een soort extern referentiepunt. Een consequent gebruik van deze informatie kan de consistentie van de beslissingen ten goede komen.

6. BESLUIT

6.1. Voorkeursscenario voor burger- en patiëntenparticipatie.

Er bestaat in de literatuur slechts weinig onderzoek over welke modellen van burger- en patiëntenparticipatie het meest effectief zijn in welke omstandigheden. Betrokkenheid heeft verschillende dimensies zoals de intensiteit, de plaats, het tijdstip, de aangewende methode en de gevolgen van de betrokkenheid.

Volgens de meerderheid van de belanghebbenden die deelnamen aan het Delphi-panel zouden het publiek en de patiënten kunnen worden betrokken op verschillende niveaus, met verschillende intensiteitsniveaus. De deelnemers verkozen een scenario van informeren en consulteren voor beslissingen over de prioriteiten voor de gezondheidszorg en over de terugbetaling van producten en diensten. Hierbij werd consultatie beschouwd als een hoog niveau van betrokkenheid, vergelijkbaar met wat we gedefinieerd hebben als deelname in het debat.

6.2. De steun die stakeholders verlenen aan burger- en patiëntenparticipatie in beslissingsprocessen in de gezondheidszorg

Uit onze studie bleek dat er een consensus bestaat over het belang van burger- en patiëntenparticipatie. Rekening houdend met het feit dat twee op de drie respondenten vandaag deel uit maakt van de bestaande beslissingsorganen inzake terugbetaling, getuigt dit een hoge mate van openheid voor verandering.

Ondanks de consensus over het belang van burger- en patiëntenparticipatie en over een positieve baten/risicoverhouding, leek er echter geen openheid te bestaan voor een volledige revisie of een grondige herziening van het huidige systeem. Veranderingen zouden moeten plaatsvinden binnen bestaande structuren. Er kan sterke weerstand verwacht worden van een kleine groep betrokkenen; op basis van de resultaten van Delphi hebben we het over maximaal 10% van de personen die hebben deelgenomen. Deze respondenten waren afkomstig uit verschillende stakeholdergroepen.

Er bestaat weinig kennis over en ervaring met het onderwerp. Dit kan een domper zetten op de positieve houding, net als de angst voor verandering en voor het onbekende bij mensen die vandaag reeds betrokken zijn bij de besluitvorming. De meeste respondenten hadden er geen idee van hoe de waarde van burger- en patiëntenparticipatie in de praktijk kan worden gecreëerd, met welke technieken en met welke soort vertegenwoordiging. Respondenten die er wel ervaring mee hadden, beoordeelden deze ervaring als overwegend positief.

6.3. Huidige en toekomstige vertegenwoordiging van burgers en patiënten

Ziekenfondsen werden beschouwd als de stakeholdergroep die vandaag de facto de (meeste) burgers en patiënten vertegenwoordigen in het besluitvormingsproces.[b] In een ideale wereld is er volgens de respondenten een veel prominentere rol weggelegd voor patiëntenorganisaties dan nu het geval is, waardoor ze op hetzelfde niveau komen als de ziekenfondsen. In deze ideale situatie werd de positie van ziekenfondsen als vertegenwoordiger van de burgers en de patiënt grotendeels gehandhaafd, wat aantoont dat de respondenten van mening zijn dat de rollen van beide belanghebbenden elkaar aanvullen in plaats van dat ze met elkaar wedijveren.

6.4. Succesfactoren voor burger- en patiëntenparticipatie

De respondenten identificeerden ook bepaalde risico's van burger- en patiëntenparticipatie. Deze (vermeende) risico's moeten in aanmerking worden genomen bij het ontwerpen van een initiatief om burgers en patiënten te betrekken bij de besluitvorming. Er moeten maatregelen komen om de risico's te beheersen en zo de slaagkansen van de participatie te verhogen. Succesfactoren zijn onder andere de opleiding van het publiek en de patiënten en andere stakeholders om efficiënt bij te dragen aan de besluitvorming, transparantie van het proces, en ontwikkeling van een participatiecultuur.

Om succesvol te zijn moet het doel van de burger- en patiëntenparticipatie goed afgestemd zijn op de gebruikte methode en de context waarin de participatie plaatsvindt. We moeten echter wel beseffen dat verschillende methoden kunnen leiden tot verschillende conclusies. Daarom is er behoefte aan systematische vergelijkingen en evaluatiestudies. Bovendien mogen de evaluatiestudies niet beperkt blijven tot een beoordeling van de resultaten, maar moeten ze ook een procesevaluatie omvatten. Participatie van burgers en patiënten is een sociaal proces, geen discrete interventie. Het vereist een voortdurend engagement van alle betrokken partijen om wederzijds vertrouwen en een zinvolle communicatie op te bouwen.

[b] Er dient te worden vermeld dat ziekenfondsen zijn in België tevens verstrekkers van gezondheidszorg, naast vertegenwoordigers van patiënten en burgers in diverse beslissingsorganen.

SCIENTIFIC REPORT

1. INTRODUCTION

1.1. Approaches for incorporating social preferences in health care policy

In a public health insurance system like in Belgium, policy decisions in health care should reflect societal values. Societal values are principles and standards of human interaction within a given group that are regarded by members of that group as being worthy, important, or significant.

Citizen and patient participation is one way to achieve this goal. Democracy should, however, not be considered as a purely ideological reason for citizen and patient involvement. From the operational point of view, decisions are expected to be better through citizen and patient involvement, i.e. more based on societal values. Of course, conditions apply for this to be the case.

Societal values are relevant on different levels of decision making. On the macro level choices need to be made about the allocation of resources between health care and other social services competing for the same limited public resources (e.g. education, retirement or disability benefits, etc.). On the meso-level, within the sector of health care with its closed budget, choices need to be made about the allocation of resources between several health conditions and health care sectors. Finally, on the micro level a reimbursement decision has to be taken for one particular product or service.

The implications of a decision on the micro level for the meso and macro level are often not clear, because the criteria are not explicit. A legitimate decision process requires that all criteria (micro, meso and macro level criteria) are weighted corresponding to their relative importance according to society. For example, if disease severity is considered more important than own responsibility for the disease, this should be reflected in the decisions taken (e.g. when injuries are the result of a free individual choice – supposing that 'free choice' can be defined and evaluated unambiguously – they should not be treated any differently from treatments for equally severe injuries due to hazard), or if preventive care is considered to be a major priority on the meso level and it is decided more resources should be allocated to prevention, the appraisal process on the

micro level should take this into account when deciding on the reimbursement of a new preventive intervention.

Several issues arise, however, when making health care reimbursement decisions:

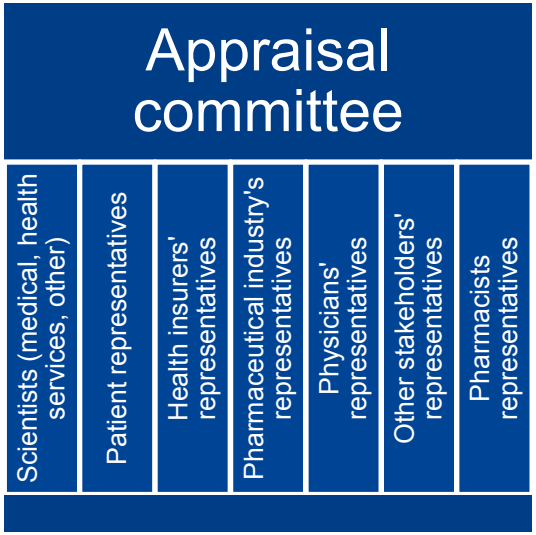
1. an array of criteria of various nature, often fraught with mutual contradictions, are relevant and have to be weighed and considered when deciding upon the reimbursement of health interventions (procedures, services, drugs). This weighing and considering is seldom straightforward;
2. the reimbursement of one particular intervention is inevitably in competition with any other intervention or any other use of the resources needed to reimburse that intervention. Trade-offs are made on the macro level between health care and other social and public services; on the meso level between several sectors within the health care system and on the micro level between several treatments for one particular disease. On each of these levels, taking a broader societal stance supported by societal needs and preferences is difficult;
3. in a rapidly evolving world, today's decision logic is not necessary applicable tomorrow.

Besides these issues, the broader societal and economic context affects reimbursement decision making. Reimbursement decisions take place within the constraints of a theoretically closed budget. However, the latter is growing at a pace that exceeds GDP growth and, hence, each reimbursement decision challenges the long-term sustainability of the social health insurance system or requires to make choices to reduce other collective expenditures. These choices are mainly implicit but should probably be more explicit. Moreover, any decision not to reimburse is at risk of causing suffering and/or impoverishment. On a wider scale it is also necessary to verify if such a decision is according to an explicit decrease of the willingness of society to further support the solidarity which lies at the basis of the system or to an explicit willingness of society to support other public services, such as education or mobility. For all those reasons, it is important that appraisal committees and decision makers in this domain take societal values into account in a more formalized way than has been the case until now. This report is an important first exploration of an issue that is at the heart of decision making.

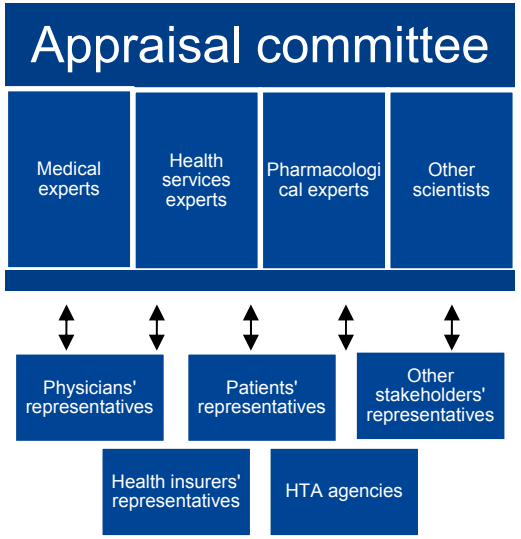
Despite the fact that health care is a domain of interest for the majority of citizens, in most countries the societal stance has only been operationalized to a limited extent. There are different approaches to incorporating societal values in reimbursement decision-making processes. A distinction can be made between two fundamentally different operational models, reflecting two different visions on decision-making processes in a democratic system: the assessment-driven model and the deliberation-driven model (see Figure 1).[3]

Figure 1 – Deliberation-driven versus assessment-driven drug reimbursement systems

Deliberation-driven model



Assessment-driven model



The deliberation-driven model assumes that by incorporating the major stakeholders in the appraisal committee, reimbursement advises will reflect societal values. This is the model currently applied in Belgium.

In the assessment driven model, the appraisal is the responsibility of mainly scientists and experts. These scientists or experts can consult relevant stakeholders if deemed necessary or systematically. The UK citizen councils are an example of a systematic stakeholder consultation round once an advice has been formulated by an appraisal committee consisting of experts. The expert committees in the UK encompass patient representatives, who bring in expertise from experience.

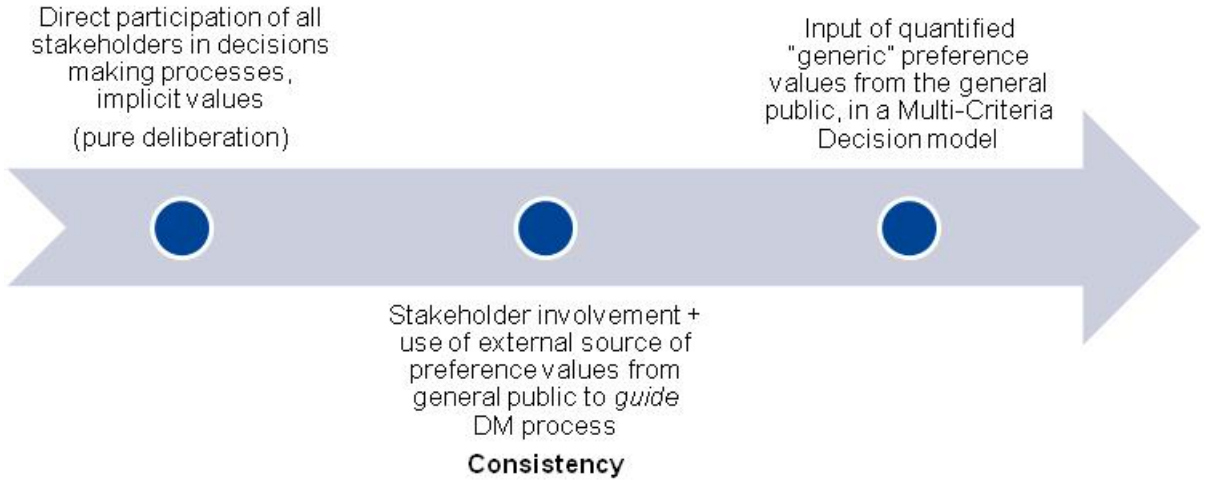
Both models have advantages and disadvantages. It should be emphasized, however, that the major difference is *not* the in- or exclusion of conflicts of interests from the appraisal process.

In both systems, societal values can either remain implicit or be made explicit. Yet very few examples exist where commissions have tried to make societal values explicit or are explicit about the weight given to each of the value criteria considered in each decision.

Whatever the model chosen, transparency in the criteria used for formulating a reimbursement advice or making a reimbursement decision is important from an accountability for reasonableness point of view.[3-11] Although it could be argued that a deliberation-driven system, where all stakeholders are represented in the appraisal committee, should in principle lead to decisions that are consistent with public values, there are very little opportunities to prove this if the criteria are not defined explicitly or not operationalised.

Therefore, an effort should be made to derive societal values for priority setting in health care from the general public. These values could then be used explicitly in the decision-making processes of appraisal committees, whatever their composition. They can moreover be used as indicators for the evaluation of citizen and patient involvement initiatives. This approach takes the intermediate position between two extremes on a continuum that defines possible levels of determinism for taking societal values into account (Figure 1). The lowest level of determinism would involve the general public directly in the appraisal process and would keep implicit the criteria used and relative weights given to the criteria. The highest level of determinism would fully quantify all preference values and weights and put these values in a multi-criteria decision model.

Figure 2 – Level of determinism of incorporating public values in the decision-making process



Citizen involvement seems relevant for both the left-hand extreme case of (lack of) determinism and the middle case, where stakeholder involvement is complemented by evidence on public preferences –as a proxy for values– with regard to criteria and relative importance of these criteria for resource use allocation.

Citizen involvement in health care policy is not new. In countries like Canada the first calls for public participation in the health care system date back to the 1970s, when citizen representation on regional health services delivery was recommended by early reports on health system reforms. It was implemented in the form of district health councils in Ontario. "*Citizen participation was viewed as a means for rationalizing, integrating and coordinating health services through local structures that could, through community representation, better respond to local health needs."* (Abelson, 2002[12], p. 73). In the UK, "*the NHS (National Health Service) Constitution states that the public have the right to be involved, directly or through representatives, in the planning of health care services, the development and consideration of proposals for changes in the way those services are provided, and in decisions to be made affecting the operation of those services*"(Cartwright and Crowe, 2001 [13], p. 18). Not only individual countries pay attention to citizen involvement, the Ljubljana charter on reforming health care in Europe (WHO) mentions the following goal: "*The citizen's voice and choice should make as significant a contribution to shaping health care services as the decisions taken at other levels of economic, managerial and professional decision-making*" (WHO, 1996[14], p.4 point 6.2.1).

Against the background of the possibility to have varying degrees of determinism, a study on the incorporation of public values in health care decision-making processes should encompass the following two topics:

1. the investigation of possible models for citizen involvement in decision-making processes and their feasibility/acceptability in the national context.
2. the investigation of actual public preferences with respect to the allocation of health care resources.

The focus of the current report is on the first research topic, while another KCE study will focus on the second. Both topics have links with previous work at KCE. KCE Report 174 defines guidelines for stakeholder involvement in KCE projects for the incorporation of public preferences in the scoping and conclusions.[15] KCE Report 147 proposed a model for making the appraisal process more transparent with a list of possible decision criteria.[3] The relative importance of the criteria for decision making has, however, not been addressed in this report.

2. SCOPE, OBJECTIVES AND GENERAL DESIGN

We limited the scope of this study to citizen or patient involvement as one technique to incorporate public values in health care priority setting and reimbursement decisions. The complementary approach, using an external reference source of public values to guide health care priorities and reimbursement decisions, will be the main focus of another KCE study.

The aims of this study are:

- to describe different models for incorporating societal values in health care priority setting and reimbursement decisions by means of public involvement in decision-making processes, and discuss the pros/benefits and cons/risks of each of these models;
- to assess the acceptability of different models for public and patient involvement for Belgian stakeholders currently involved or not involved in health care decision-making processes.

The ultimate aim is to assess whether Belgian stakeholders consider public and patient involvement in health care priority setting and reimbursement decisions acceptable and if so, identify the preferred model for public and patient involvement in health care policy in Belgium. We aim to formulate, based on our empirical findings, realistic recommendations for public and patient involvement in health care policy in Belgium. A specific methodology was used for each research question. Existing and potential models for public and patient involvement in health care policy, with their pros/benefits and cons/risks were identified through a literature search. The acceptability of different models for public and patient involvement in a Belgian context was evaluated through consultation of different stakeholders. A two round Delphi approach was considered appropriate as this allows to involve a rather large group of people (potentially) involved in several types of decisions, to gradually narrow down among the many potential options, and to search for potential consensus among participating experts. Methodological details for each part of the study are provided in the respective chapters.

2.1. Justification of the chosen scope

Consideration of public and patient involvement in several layers of decision making in health care has been put high on the agenda of several national and international organisations, such as the World Health Organisation (WHO), the King Baudouin Foundation (KBF)[c] and the National Institute for Health and Disability Insurance (RIZIV – INAMI)[d]. The quest for incorporating public preferences in public decision-making processes is not new, but becomes more and more explicit in democratic societies for which the individual freedom of choice is considered a fundamental right. Freedom of choice is recognized as a minimal requirement for individual responsibility, which is more and more considered to be the concept that basically expresses the foundations of a modern society. In the words of the Nobel price Amartya Sen[16] 'the liberty is the necessary and sufficient condition for responsibility' (p. 372).

The concept of individual responsibility may become particularly important in the context of concerns about the growth of public health expenditures. The argument of individual responsibility may be used by the decision maker to define the part of the health care costs to be paid by the patients themselves (i.e. patient cost sharing). This can be either because the decision maker feels that patients should be made conscious of the costs they impose upon the society, or because he feels the patient can –at least partially, and if he/she is recognized as being free be held responsible for his/her own health condition, resulting from his/her behaviour or lifestyle.

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c The King Baudouin Foundation (KBF) is an independent, pluralistic foundation. KBF aims to make lasting changes towards greater justice, democracy and respect for diversity. Within the health area, KBF supports initiatives that promote health, increase the quality of life of patients and their environment and contribute to a high quality, accessible and socially acceptable healthcare.

d The RIZIV – INAMI organises, manages and supervises the correct application of the compulsory health insurance in Belgium. The RIZIV – INAMI is supervised by the Minister of Social Affairs.

The Belgian health care system is largely based on principles of solidarity. Compulsory health insurance covers a large majority (approximately 78%) of the nationally consumed health care products and services. This coverage rate is the result of the long-standing Belgian consultative model for making reimbursement decisions. The issue of public and/or patient involvement emerges almost naturally in a system where every citizen contributes to the available public resources for health care as a taxpayer and a payer of social contributions on the one hand, and as a patient in the form of direct co-payments on the other hand.

The KBF has taken multiple research initiatives relating to public and patient involvement in the Belgian health care system, and continues to develop this field of research.[17-19] To expand on particular questions, the KBF submitted a research topic proposal to KCE together with the RIZIV – INAMI. The RIZIV – INAMI is directly concerned by a debate on public and patient involvement, as its outcomes might have a direct impact on its daily activities. Therefore, we preferred to define the scope of our study taking existing structures, such as advisory committees, and decision-making bodies and methods into account. Our initial focus was on drug reimbursement decision-making procedures because it seemed particularly interesting to consider public and patient involvement in this context. In Belgium, the drug reimbursement committee that advises the final decision maker (the minister) is composed of representatives of the medical community (providers), sickness funds, universities, pharmacists, drug industry, the ministry of social affairs, of public health and of economic affairs and RIZIV – INAMI. Representatives of the drug industry, the ministries and the RIZIV – INAMI do not have voting rights. Assessment reports prepared by RIZIV – INAMI experts are discussed in the drug reimbursement committee leading to the advice. However, the representation of various stakeholders in the drug reimbursement committee does not imply that decisions are taken in line with societal values. Additional requirements apply. Although some of the current stakeholder representatives can be considered as representing the patients or the general public, it has never been defined formally by law which stakeholder, amongst those with voting rights in this committee, should take the explicit role of the Belgian citizen as taxpayer or the patient as health care consumer. Moreover, the patient as expert by experience is currently not involved in the committees, nor involved in the assessment procedure preceding the appraisal by the committee. No formal procedure is in place to ensure that advices formulated by the expert committees are in line with social preferences. There might be room for more explicit and formal public and patient involvement in the current decision-making structures. However, to be able to make judgments about the feasibility of it, more evidence regarding the acceptability is needed, either to anticipate potential future problems of implementation or to reconsider models of involvement.

Besides this, reimbursement (or not) of pharmaceutical and other health care products are attractive for the media, as decisions regarding such products generate questions and emotions.

The drug reimbursement procedure can not, however, be considered in isolation from higher level strategic decisions about health priorities. The national fee system for health care services (nomenclature) is a positive list of fully or partially reimbursed services. The list is dynamic, meaning that services can be removed or added and reimbursement rates can be modified. The decision to add or remove services from the list or to modify the reimbursement tariff is taken by the Minister of health, who is advised by the competent advisory committee at the RIZIV – INAMI. While effectiveness, efficiency, and accessibility are common decision criteria for several types of decisions in health care (e.g. regarding drug reimbursement, physician fees, dentistry, nursing, ophthalmology, rehabilitation, elderly homes …), they also have a particular meaning for each of these and should, overall, take social choices with respect to priorities into account. Given the rather technical nature of the decisions to be taken, however, the involvement of the public and patients may provoke resistance from the current, well-organised, stakeholders involved in the decision-making process. It seems therefore useful to test the conditions for a potential involvement of the public and patients in different forms and at different phases of the decision.

For these reasons, we enlarged our scope to strategic decisions with respect to priorities for the allocation of health care funds.

2.2. The Belgian context

The design of the study as well as its results should be situated within the context of the Belgian health care system (compulsory health insurance). According to the budgetary data of 2011, about 60% of the total public health care expenditures are financed by social contributions (proportional to income), 20% by income taxation (progressive) and 20% by taxes (mainly Value-Added Taxes). These public expenditures cover less than 80% of the overall health care expenditures, that also consist of co-payments by patients, several supplements and non-reimbursed products and services.

A number of advisory committees within the RIZIV – INAMI, which are composed by representatives of different health care sectors, representatives of sickness funds and representatives of the RIZIV – INAMI, define the budgets for each health care sector and the reimbursement lists within each sector. A convention commission exists for the majority of the health care sectors (e.g. the convention commission physicians and sickness funds (Medico-Mut) and the commission of dentists and sickness funds) but also three non-sector-specific commissions (commission of budgetary control, the insurance committee and the general council).

The sum of all sector-specific budgets is not allowed to surpass the global envelop. The growth rate of the global national budget is determined by law. The competent authorities have to guard, each year, whether the budget remains within the imposed limits by establishing the tariffs (i.e. the 'prices' of the service or product) and the part of these tariffs paid by the RIZIV – INAMI. The patient share is defined as a fixed amount (co-payment) or as a percentage of the tariff (coinsurance). If the budget is sufficient, the list of reimbursed products and services can be extended. In contrast, in case the budget risks to be exceeded, cost saving measured must be taken. These can be either specific for particular products or services or more structural.

This general description of the organisation of the Belgian health insurance shows that choices have to be made constantly in an ever-changing sector. With a seemingly never-ending stream of new products and services, criteria for taking decisions regarding which ones should be covered from public resources need to be applied in the decision-making process. The public and patient could be involved at different levels and in different stages of this process, from the definition of the global priorities amongst sectors with public financing (e.g. education versus health), the sources of financing for the health insurance (e.g. taxes versus social contributions) to the reimbursement of an orphan drug and the choice to allocate resources to intellectual versus technical health care services.

3. LITERATURE ON PUBLIC AND PATIENT INVOLVEMENT IN HEALTH CARE POLICY

Key questions

What is public and patient involvement?

In what **context** does public and patient involvement take place?

What are the **motives/rationales** for engaging the public in health care decision making?

Who should participate?

In what **types of decisions** might citizens-patients be involved?

What is the **validity** of measuring public preferences/opinions?

What are the **key dimensions** of public and patient involvement?

What is the **effectiveness** of public and patient involvement?

3.1. Work strategy for the literature review

The focus of this comprehensive review of the literature is on areas of public involvement in health care decision-making, priority-setting and resource allocation. In addition to the growing body of literature on public and patient involvement these domains and in health care policy in general, a number of literature reviews on patient and citizen involvement are available, for example from the Bertelsmann Foundation[20], but also from the King Baudouin Foundation, the initiator of this research project.[17-19] We took these reports, including the references they cite, as the point of departure for our own narrative review. In a next step we continued selecting the most relevant references from the articles we read, resulting in a snowball sample of scientific articles. Articles were included if they added new information or fresh insights. Throughout our literature review we were especially interested in (1) empirical studies of public and patient involvement and consultation methods, practice and evaluation, and (2) theory and conceptual frameworks regarding the design and evaluation of public and patient involvement processes. This literature review is by no means the result of a systematic literature search. In addition to introducing the reader to the topic of public and patient involvement, the literature review should help to position this report within the public and patient involvement literature as a whole, to define the concepts we use throughout the report and most of all to prepare for the Delphi study, which is the core element of our study. The aim was to identify key ideas, concepts and debates in order to develop a better understanding.

We excluded studies that examined involvement in terms of service development, shared decision-making of individual treatment, clinical decisions, therapeutic and service delivery decisions, and clinical guidelines. We also excluded studies about public and patient involvement in health research or non-health fields such as environmental sciences and urban planning. This was done, not because we thought this literature was irrelevant, but mainly because of time limitations.

The literature was read with an analytical purpose in mind. In first instance we tried to unravel the complexity of public and patient involvement into its constituent parts. We clustered the information in a number of themes or key issues being addressed throughout the literature. These issues related to the definition, context, motivations, validity, dimensions and effectiveness of public and patient involvement. We made those the guiding principles of the text to follow.

3.2. Definition of public and patient involvement

There is a multiplicity of terms indicating variations on and kinds of public and patient involvement: citizen involvement, patient participation/involvement, lay participation/involvement, public participation/involvement, community participation/involvement, citizen empowerment, public engagement, public opinion, citizen engagement, citizen consultation, and citizen communication, to name just a few. With such a range of quasi-synonyms, a large number of definitions is not surprising. In addition, the enormous literature on public and patient involvement crosses both subject and disciplinary boundaries.

The *International Association for Public Participation (IAP2)* defined public involvement in the following way: "'*Public participation' means to involve those who are affected by a decision in the decision-making process. It promotes sustainable decisions by providing participants with the information they need to be involved in a meaningful way, and it communicates to participants how their input affects the decision*." (www.iap2.org, 24/02/2012).

However, this definition has been criticized. Together with the IAP2 core guidelines (see Table 1), the definition does not really embrace public contributions beyond 'interests' and 'needs'. It is overlooked, or at least not said explicitly that in addition to requiring information, the public might also have some information to contribute. The IAP2 definition and guidelines are criticized for primarily being a matter of contextualizing or even legitimating expert-determined decisions and the status quo they reflect rather than empowering the public.[21]

Table 1 – Guidelines for public participation

1	Public participation includes the promise that the public's contribution will influence the decision.
2	The public participation process communicates the interests and meets the process needs of all participants.
3	The public participation process seeks out and facilitates the involvement of those potentially affected.
4	The public participation process involves participants in defining how they participate.
5	The public participation process provides participants with the information they need to participate in a meaningful way.
6	The public participation process communicates to participants how their input affected the decision.

Source: www.iap2.org, 24/02/2012

Despite a growing body of literature on public and patient involvement, the concept of public and patient involvement remains poorly defined. This goes together with conceptual vagueness throughout the literature concerning who are the 'public' and 'patients' in public and patient involvement and which roles they can take in the decision-making process. Which actors are involved is considered here to be an analytic choice. The 'public' may refer to citizens, consumers, tax or social contributions-payers, lay people, service users, and patients. Every citizen is a patient, a service user, a consumer of health care services and a tax or social contributions-payer. Being a 'citizen' or a 'patient' is not a status, but rather a role one adopts in a specific context. It depends on the content of the questions a person has to answer and the perspective he/she (has to) adopt(s) when answering the questions whether he acts as a citizen or a patient. The citizen cannot be 'separated' from the patient because every citizen can/will become or has been a patient at a certain moment in time. This approach is similar to Coulter (2002) who argues that the distinction between public and patient is artificial and that the public includes patients and those who may become patients in the future. In addition, individuals easily move between roles;[22] Other authors, however, differentiate between public and patient involvement. For example Florin and Dixon

define patient involvement as referring to "*decisions about one's own care*" only (Florin and Dixon, 2004[23], p. 159).

Throughout this report we will consequently use 'public and patient involvement' because we want to link this concept to the two dominant roles representatives of the public can fulfil. Which role representatives take depends largely on the perspective chosen: (1) that of a health services user or (2) that of public policy 'agent'. The first reflects a concern with the potential impact of a decision on the individual patient's interests, the second with some notion of a broader public interest.[1] If the perspective of the health services user is taken, the group of (potential) patients in general is represented, defending patients' interests, even if the representative is not a patient himself. If the perspective of the public policy 'agency' is taken, the representative will defend broader societal interests. Mitton et al.[24] (p. 223) linked the ways in which citizens can participate in decision-making processes in a public policy perspective to three definitions of 'the public': (1) the public as individual citizens speaking on their own behalf, (2) the public as organised interest groups supposedly speaking on behalf of their membership, and (3) the public as patients or consumers of services. We prefer using the term public and patient involvement in order to maintain the principle that both citizens and patients can be organised and speak on behalf of their membership (either society or the group of patients in general). In addition, we prefer using 'public and patient involvement' because the Delphi survey also differentiates between the 'public' and 'patient' perspective (see chapter 4).

The term 'involvement' is problematic in the sense that it is used interchangeably with a number of other terms, such as participation, engagement or even empowerment even if empowerment can rather be considered as a consequence of involvement. Conklin et al. (2010) associate involvement with "*activities beyond routine democratic processes*" (Conklin et al., 2010[20], p. 2). In this report we also use 'involvement' as an umbrella term defined as "*the spectrum of processes and activities that bring the public into the decision-making process*".(Conklin et al., 2012[20], p. 2)

3.3. Key features of public and patient involvement

Three key features of citizen and patient involvement can be distilled from the discussion on what is public and patient involvement.

First, involvement is **context specific** and may take many forms.[25] Therefore, it is difficult to come to one overarching general definition. Laverack and Wallerstein[26] emphasize that any definition or typology of involvement should reflect multiple organisational domains of empowerment. These domains refer to the social economic and contextual factors that influence the participation process and are often critical to its success.[25] The context specificity of public and patient involvement leads to a paradox: at the one hand there is a need to formulate or derive principles of involvement that can be generalized and applied across a variety of national and political environments (standardization), but at the other hand participation methods need to be sensitive to and adaptable to local circumstances.[27]

Second, public and patient involvement is a social **process**, not a discrete intervention.[25, 27] Nelson et al.[28] argued that participatory processes require some degree of "*on-going engagement to develop meaningful communication and trust*" (p.44). In this regard, it should be noted that the prioritization process in health care decisions is also dynamic and ongoing. In the well-known Oregon case "*a new priority list is generated each budget cycle to take into consideration new technologies and new information on outcomes*" (Kitzhaber, 1993[29] p. 375). Each time the Health Services Commission sets up a broad based public process to identify and integrate societal values into the priority list.[29] The ongoing character of participation implies the need to institutionalize public and patient involvement. As Oakley et al. (1999)[30] put it, participation "*has to be systematically encouraged, and means have to be created to make it effective*" (Oakley, 1999[30] p. 117). A difficulty arising from the process approach is that no fixed endpoint can be defined, hence evaluation of public and patient involvement in terms of its success or effectiveness becomes rather difficult.

Third, participation is about **power**[27] and how power is distributed among stakeholders. "*The call for greater lay participation suggests first, and perhaps foremost, a shift in political philosophy about who has the right to make what health care decisions in whose interests. The shift is toward a more democratic and participatory process of decision making and away from professional (particularly medical) dominance. At a policy level, it reflects a view that providers' technical expertise does not give them any informational advantage when it comes to the numerous value considerations central to today's health care resource allocation decisions."* (Charles and DeMaio, 1993[1] p. 883-884*).* Different actors (e.g. health care professionals versus patients) have different (power) positions within the health care system, different interests and resources such as knowledge and frames of reference (expert or lay).

In sum, the meanings attached to public and patient involvement are plenty and depend on the predefined goal (optimizing the consequences of decisions, empowerment or capacitating, see 3.4), the context in which it is applied, the intensity of the participation model (see 3.6.2), and the actors involved.

3.4. Rationales for public and patient involvement

Key questions

Why should we bother about public and patient involvement?

What can we attain by engaging the public in health care decision-making?

What do we want to attain by engaging the public and patients in health care decision-making?

There can be multiple rationales for public and patient involvement, depending on the perspective taken. We distinguish three main and two additional perspectives:

1. The **consequentialist, technocratic or consumer perspective** describes participation as 'a means to an end', the end being the achievement of policy goals, such as more effectiveness and efficiency in health care.[31] It can easily be linked with particular public and patient interests. A definition of involvement in line with this perspective is provided in a the WHO publication, written by Kahssay and Oakley (1999[32] p. 5): *"(…) participation as 'collaboration', in which people voluntarily, or as a result of some persuasion or incentive, agree to collaborate with an externally determined development project, often by contributing their labour and other resources in return for some expected benefit."* The utilitarian perspective, being a particular case of consequentialism, limits the 'motivations' of an individual to an expected benefit or utility for themselves or for society.
2. The **empowerment, emancipation or democratic perspective** is driven by general democratic principles instead of particular interests. Participation is "an empowerment tool through which local communities take responsibility for diagnosing and working to solve their own health and development problems" (Morgan, 2001[27] p. 221). Participation is described as 'an end in its own right'[31], or as valuable per se.[33] Charles and DeMaio (1993[1] p. 888) conclude "Clearly, there is a desire for a more participatory and democratic health care decision-making process in which the medical profession and other dominant interests would no longer play so predominant a role."
3. The **individualistic, capacitating perspective** focuses on the freedom and sense of responsibility of the individual as the primary goal. This concerns directly the citizens and patients participating in a collective process. We can consider that this perspective builds on the concept of capability (the set of beings and doings of an individual) as introduced by Sen and Nussbaum.[34-43] From this perspective, the citizen has the capability to make choices, he is free to choose and can be held responsible for its choices. This perspective is linked to the goal of the 'legitimation' of decisions. In contrast to the consequentialist perspective, which is driven by individual and societal benefits of outcomes, the capacitating perspective presumes that individuals can be 'motivated' by others sentiments like altruism, generosity not taken into account in consequentialist models.[44]

Conklin et al. added two additional perspectives:

4. In the **developmental** perspective involvement is interpreted as "*a means to increase citizens' capability and confidence for political engagement, (and) their understanding of the challenges of policy-making (…)*" (Conklin et al., 2010[20], p. 3).
5. The **critical perspective** questions the ultimate purpose of public and patient involvement, saying that it provides greater credibility for something decision-makers would have done anyway, also referred to as tokenism. It allows politicians to "deflect criticism by suggesting a broader consensus" (Rutter et al, 2004[45], p.1973).

Tensions between these different perspectives and consequent rationales for involvement derive in part from contrasting ideological and political values and also concepts of citizenship.[25] For example, should the purpose of public and patient involvement in health care decision making be the improvement of service delivery and quality of care, or should it be linked with broader concerns such as equity and citizenship?

In literature, plenty of reasons are cited to engage the public in health care decision making. Without claiming to be exhaustive, we clustered them into four goals. These goals more or less converge with the discourses Becher et al.[19] distil from interviews with stakeholders in the Belgian health care system on public and patient involvement, being (1) the improvement of quality of care, (2) the legitimation of health care decisions, (3) representation, (4) to promote trust and confidence in the health service and (5) to tackle health inequalities and to engage communities and individuals in health action.

GOAL 1: The improvement of quality of care

- "*In order to reach more cost-effective care*" (Wiseman et al., 2003[33] p. 1003).
- "*To improve the quality and reliability of services*" (Wiseman et al., 2003[33] p. 1003).
- "*It allows for services to be 'culturally sensitive and builds on local knowledge and expertise*" (Wiseman, 2003[33] p. 1003).
- "*To make providers more accountable to the communities that they serve*"(Charles and DeMaio, 1993[1] p. 889).
- "*To encourage providers to think more carefully about the objectives of health services and to be more open and explicit about the choices being made*." (Wiseman et al., 2003[33] p. 1003).
- "*To allow organisations to target services more effectively in response to felt and expressed needs*" (South et al., 2005[46] p. 65).

Most reports calling for increased public and patient involvement assume that it will lead to better decision making in health care, often without explicitly defining what this might mean, but in fact there is little empirical evidence that it does so.[1]

GOAL 2: Legitimation of health care decisions

- "*The desire to achieve popular support for potentially unpopular decisions*".(Abelson et al., 2003[47] p.239).
- "*An additional motivation is the belief that more effective public participation techniques might foster, or even act as a substitute for social capital, seen as necessary for improving governance (broadly and in the health system) and manifested through collaborative problem solving among citizens in communities and organisations (Putnam, 1993; Veenstra & Lomas, 1999)*" (Abelson et al., 2003[47] p.240).
- "*To ensure local accountability for services*". (South et al., 2005[46] p. 65).
- Participation is also a way for citizens **to adhere** to the system, and **to accept** the consequences.[48, 49]

GOAL 3: Representation

- "*People are openly questioning the right and competence of politicians, professionals and bureaucrats to take decisions on their behalf*" (Wiseman et al., 2003[33] p. 1003).
- "*To bring different types of knowledge to decision-making processes which can be considered 'equal even if different*"(Charles and DeMaio, 1993[1] p. 898).
- "*A search for local understanding rather than universal truths*" (Wiseman et al., 2003[33] p. 1003).

- "*Greater awareness of consumer rights in health care*"(Wiseman et al., 2003[33] p. 1003).
- "*Citizens have the right to participate; this is linked to the notion of social justice and the democratization of health and health care*" (South et al., 2005[46] p.65). Participation can be considered as a necessary condition for social justice (if this participation is really democratic) but certainly not as a sufficient one.

GOAL 4: To promote trust and confidence in the health service (e.g. Wiseman et al., 2003[33] p. 1003)

Citizens and patients are encouraged to think more carefully about the objectives of health services and the choices being made. They experience from close by how decisions are made.

GOAL 5: To tackle health inequalities and to engage communities and individuals in health action (e.g. South et al., 2005[46] p. 65)

Also minorities or marginalised groups should be represented, informed and consulted. This way health care providers and decision-makers may get more insight in their unmet needs. If informed these groups may be empowered in their use of health care services.

Key points

- **The empowerment rationale describes public and patient involvement as an end in itself.**
- **The consequentialist rationale defines public and patient involvement as a means to another end.**
- **The capacitating rationale describes public and patient involvement as a means to give the population the opportunity to be responsible.**

3.5. The context of public and patient involvement

Key questions

Why is public and patient involvement on the rise?

Which contextual attributes do we need to take into account when selecting a participation method, and by extension a participation scenario?

How are processes of public and patient involvement shaped by the context in which they are implemented?

3.5.1. Why is public and patient involvement on the rise? Societal characteristics and tendencies

Several societal characteristics and tendencies are being associated with the actual popularity of public and patient involvement in general, but also in the Belgian context. Leys et al.[18] mention a higher average level of education, higher patient expectations regarding health care, both in quality and quantity, and increasing financial constraints. The latter two give rise to a tension that is caused by, amongst others, ageing, medicalisation of society and fragmentation of health care needs.[19] Scarcity of resources necessitates (difficult) choices to be made by governments. Involving citizens and patients is an attempt for legitimation. Increasing financial accountability of the patients legitimates an increasing public and patient involvement in the decisions, choices and priority setting in health care.

Although this applies less to the Belgian situation with a strong medical profession, there is also a theoretical link with the 'deprofessionalisation' of medicine. A higher educational level of the general population, high patient expectations, a demand for high quality care are eroding the characteristics of the medical profession, for example the monopoly over specialized knowledge. The knowledge, information, risk and consumption society have changed the power relations between health care professionals and patients, as well as within the medical profession. In this regard, "*The call for lay participation [has not only been one of]*

empowering an oppressed group but subordinating a dominant one." (Morone, 1990[50], p. 253, cited in Charles and DeMaio[1], 1993).

3.5.2. What constitutes the context of public and patient involvement?

Public and patient involvement cannot be defined outside of a social context (Muller, 1991[51], cited by: Morgan, 2001[27]). This is emphasized by many authors (e.g. Morgan, 2001[27]; Abelson et al, 2007[52]), but each give their own interpretation of what constitute context. It is referred to as for example the national and political environment, or the health care system, or even more abstract "*the social relations and matrices of power through which participation must be effected*" (Morgan, 2001[27] p. 225). Typically it is defined in broad terms as the setting or environment within which a health care service or intervention is delivered. However, as Abelson et al.[52] state the elaboration beyond general depictions of context in community, cultural, organisational and political terms has been rare. Nevertheless, in order to implement successful public involvement, it would be good to know which contextual characteristics matter most.

Abelson et al. (2007[52] p. 2119) provide a typology of contexts and explored their potential impacts.

- Political context: e.g. historical relationships and trust among governors and community/public
- Community context: e.g. characteristics of the population, geography, political participation, social capital
- Researcher-decision maker relationships: e.g. new or on-going partnership deference to "academic expertise"; receptivity to innovation and experimentation
- Organisational context: e.g. constraints, level and magnitude of commitment to the project, attitude of key organisational staff
- Decision-making context: e.g. decision making procedure, responsibilities of different actors, types of issues, stage and overall time frame of decision-making process

3.5.3. The role of context in the choice of a public participation method: still an unknown territory

Several authors[18, 52] conclude that a close match between participation method and context is crucial for public and patient involvement to succeed, but more research is necessary to know which method is most effective in which circumstances.[53-55] "*Attention to these contextual attributes and to their influence on public participation design and outcomes is as important as choosing the "right" public participation mechanism." (*Abelson et al., 2007[52] p. 2126). Mitton et al. (2009)[24] (p. 227) conclude their review with "*further study is needed before there is sufficient evidence to make such recommendations as 'if your circumstances are similar to situation X, then Y or Z approaches to public engagement appear to have been successful in the past'*."

Key points

- **Public and patient involvement is part of the answer to a number of societal developments, such as an increasing demand for health care and financial constraints.**
- **We need to take into account the political, community and organisational context, in addition to the characteristics of the decision-making process and the researcher-decision maker relationships when selecting a participation method, and by extension an involvement scenario.**

3.6. Key dimensions of public and patient involvement

Key question

What are the key-dimensions of public and patient involvement as represented in the literature?

Experts in public and patient involvement often describe involvement or participation as complex concepts. The following two statements exemplify this:

"In practice, community involvement remains a complex and contested concept and this complexity creates significant methodological and practical challenges as to how it can be evaluated and what indicators can be used to measure progress (Barnes, 1999)" (South et al., 2005[46] p. 65).

"The complexity of community involvement practice which can vary with context, organisation, level of decision making and diversity of community needs, all makes measurement difficult." (South et al., 2005[46] p. 69).

In order to grasp the complexity of public and patient involvement we tried to deconstruct it into a number of key dimensions as represented in the literature. These are (1) the level of participation, (2) the intensity of participation, (3) the type of actors in the participation process and (4) the relationship between actors.

The goals or aims of public and patient involvement could be proposed as a fifth key dimension, but since it relates to the broader concept of participation, we already described this in 3.4 (rationales for public and patient involvement).

3.6.1. The LEVEL of participation

With the level of participation we refer to the policy level or health care decision-making domain. In other words, the level at which the health care decisions, for which participation is organised, are taken. Mitton et al.[24] follow the basic triptych – macro, meso, micro level in health care decision making:

- MACRO (federal and regional policy makers). In their scoping review Mitton et al.[24] have defined this level of decision making as "*relating to broad strategic directions or overarching policies and general budget allocations*" (p.221)
- MESO (health care organisations and institutions + local policy makers). In the same study, this level was described as "*priority setting or allocation within particular categories of programs or services*" (Mitton et al., 2009[24] p.221)
- MICRO (interaction between health care professional and health care user (not necessarily a patient). In the Mitton study[24], this level was excluded from the review.

Similarly, Charles and DeMaio[1] distiguish between (1) broad macro-level decision-making contexts, (2) service delivery and (3) treatment. The first sub-domain is about macro-level health care allocation and policy decisions taken for a broader jurisdiction such as a nation or province, the second relates to resource allocation decisions for a defined region or a particular health care facility, and the third refers to decision-making regarding treatments or services.

In one of the King Baudouin reports[18] the following policy levels are taken into account: (1) international, (2) national, (3) regional, (4) local organisations and finally (5) patient-carer interaction.

Lomas[56] presented a three-level scale to assess the scope of public engagement, with (1) the highest or macro level relating to which services should be funded (general principles of organisation), (2) the meso-level relating to specific services and programs, and (3) the third level relates to decisions about the terms under which patients should receive services.

3.6.2. The INTENSITY of involvement

The intensity of involvement is "*the extent to which individuals have control over the decision-making process*" (Charles and DeMaio, 1993[1] p. 893). A broad range of levels of involvement has been well documented in the literature. A number of typologies of public and patient involvement have been developed that are based on a continuum of power sharing of which Arnstein's ladder is probably the most famous[57].

Arnstein (1969) ranks the different degrees of public and patient involvement starting at the lowest level of participation and ascending upwards to the highest level of participation, citizen control in which power is directly transferred from the government to the people. Following Arnstein a number of similar models or typologies have been developed including those developed for use in specific contexts. Examples are the participation ladder of Thomas, or the model of Edelenbos and Monnikhof, or Shand and Arnberg, or OESO, or the Health department of Canada. For a comprehensive overview of these participation typologies, see Leys et al.[18], one of the King Baudouin Foundation reports on patient participation.

In general public and patient involvement is represented as a continuum ranging from "informing" as the minimum level and "decision making/controlling" as the maximum level of involvement, which each level including the previous one. Methods differ in terms of the direction of information flows, uni-directional (such as informing) or bi-directional (such as shared decision-making). Most typologies suggest a hierarchy: the more intense participation is, the more power participants have and the more valuable the participation is supposed to be.[18] Most models are one dimensional (except the participation ladder of Thomas, who takes the type of actor into account in addition to the intensity of the participation), do not take contextual factors (such as goals of a health policy) into account and are very general.

Mitton et al. (2003)[24] used three levels or intensities of engagement: communication, consultation and public participation (p. 220), adopted from Rowe and Frewer[58].

- **Communication** is a one-way transfer of information from the decision-maker to the public[24] (p.224).
- **Consultation** means information is provided by the public to decision-makers, but without interaction or formal dialogue[24] (p.224).
- **Participation** implies that through dialogue and deliberation opinions of members of both parties are transformed[24] (p.224).

Very similar to Mitton et al. (2009)[24], Abelson et al. (2007)[52] identify three major groupings of methods, based on the intensity of participation:

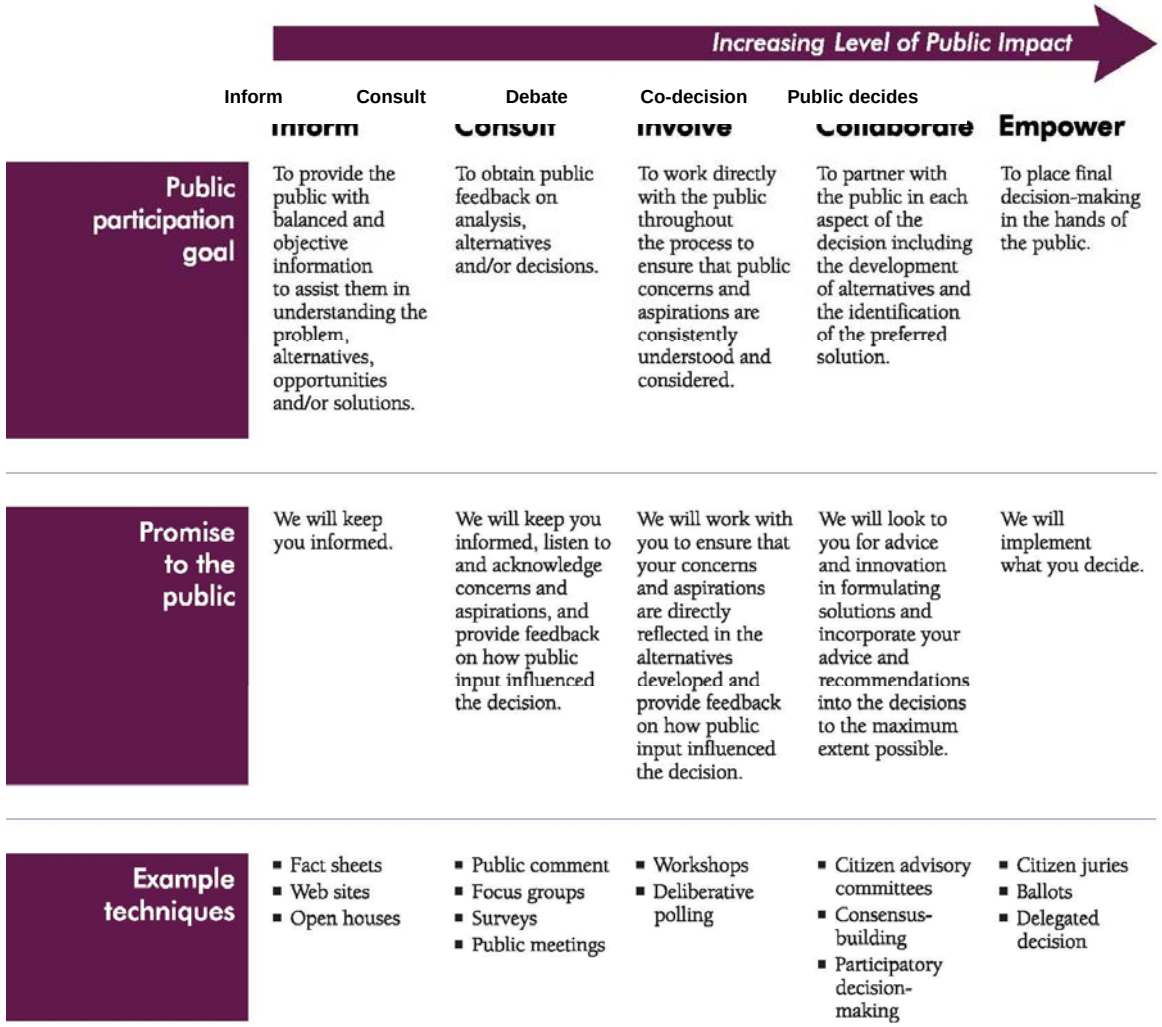
- **Citizen communication**: the public as recipients of information.
- **Citizen consultation**: the public as consultants
- **Citizen engagement**: the public as full and equal partners in decision-making

Also the International Association for Public Participation (IAP2) developed a typology showing similarities with the model of Edelenbos and Monnikhof and the Health department of Canada (see Figure 2).

However, these hierarchical conceptualisations of involvement have also been criticized for focussing on power to make decisions as the sole measure of involvement.[59] Tritter and McCallum[59] argue that a more nuanced model is required, which incorporates the process as well as outcomes of public and patient involvement, the importance of methods and feedback systems. Rather than a ladder-based model, they propose a mosaic analogy to aid understanding of how public and patient involvement can be implemented. "*This analogy captures interactions between individual users, their communities, voluntary organisations and the health care system on which successful user involvement depends.[…] The mosaic illustrates the relationship between horizontal and vertical accountability and enables user involvement to be mapped and monitored*" (Tritter and McCallum, 2006[59], p; 165).

We tried to take into account this critique by conceptualising the intensity of involvement as one dimension of involvement amongst others, such as the type of actors involved, the relationships between actors and the level of involvement In addition, a number of authors have criticized the hierarchical approach to public and patient involvement. For example, Litva et al. (2002) showed that the preferred intensity of involvement of members of the public lies between consultation and "involvement", where involvement is defined as a kind of partnership with responsibility for decision making shared between professionals and the public.[2] Consultation refers to "*an opportunity for individuals to express their views, but offer[ing] no guarantee that individual views will be taken into account*" (Charles and DeMaio, 1993[1], cited by Litva et al., 2002). Litva et al. (2002) conclude that there is a considerable gap between these degrees of participation. The informants in their study wanted their involvement to be located within this gap.[2]

Figure 3 – The IAP2 spectrum of public involvement



Source: Adapted from [http://www.iap2.org/associations/4748/files/IAP2%20Spectrum_vertical.pdf,](http://www.iap2.org/associations/4748/files/IAP2%20Spectrum_vertical.pdf) 27/08/2012

3.6.3. The type of ACTORS

In this paragraph on the type of actors we are especially interested in the question who to envision when talking about participation: citizens, the public, patients, and/or consumers? Related to this is the question of who could represent them.

Becher et al.[19] empirically identified four types of actors potentially involved in participation initiatives:

- Citizens or everyone who is paying taxes. Citizens or the public are assumed to defend the collective or public interest.
- Pre-patients or everyone who potentially can become ill or disabled. This group of potential patients represent the prevention or risk perspective.
- Patients or everyone who deviates from the medically defined norm of health. In this group a distinction is necessary between chronic and acute patients. Note that patient organisations represent mostly chronic patients. Acute patients are underrepresented and often not able to participate. In addition the patients are assumed to defend a particular patient interest that is focused on specific pathologies. In Belgium, patients are traditionally represented by sickness funds with, for some of them, a specific attention for chronic patients. Recently, specific patient organisations have expanded the organised representation of patients.
- Consumers or everyone who is in contact with the health care system. Consumers defend the consumer interest, which differs from the patient interest in that patients are seen as dependent on care and care givers, and are not able to choose, while consumers have freedom of choice.

Actors involved in health care decision making can adopt two fundamentally different role perspectives: (1) that of a health services user and (2) that of a public policy perspective. The first reflects a concern with the potential impact of a decision on the individual patient's interests, the second with some notion of a broader public interest.[1] Note that actors can be organised into groups or associations (e.g. patient or consumer organisations), or be unorganised (e.g. general public).

Public and patient involvement can involve multiple publics at the same time and can pay special attention to disadvantaged groups. "*Such groups traditionally have not been involved in decision-making, and they may have concerns or needs of the system which may not be adequately identified through a general consultation process.*" (Mitton et al., 2009[24] p. 224). Note that when participation is broadly defined and open to all it often becomes unequal (Adams, 1989), as certain groups will not be able to represent themselves. This observation leads to the question of whether disadvantaged or vulnerable populations should be approached with unique or modified participation methods.

This brings us to the question who represents or could represent citizens and patients. A distinction can be made between on the one hand 'traditional' actors in health-care decision-making such as sickness funds and professional care providers and on the other hand patient or consumer organisations.

The sickness funds take a key position in the Belgian health care system. They defend the interests of their members, hence represent citizens and patients.

Also professional care givers can claim being the representative of their patients. As they are in direct contact with patients they know their needs. Also professional care-givers organisations face a conflict of interest, since their private interests do not always converge with patients' interests.

3.6.4. Relationships between ACTORS: how to address power inequalities?

Especially if deliberative participation methods are used, actors involved in the participation process are not independent, but stand in relation to one another. Relationships between actors are especially relevant regarding the power inequalities that characterize them. Actors (not restricted to participants, also initiators of the participation process) differ in terms of the resources (e.g. social capital, knowledge) they can use.

Relationships and inequalities are closely linked to concrete participation methods and are especially relevant regarding ***deliberative participation methods*** (e.g. focus groups) during which participants meet each other. Abelson (2003)[47] asks "*Can power or status inequalities among participants be excluded from the deliberative dialogue*?" (p. 241). Healy (2009) states: "*While current mainstream approaches to public participation explicitly promote inclusive dialogue and deliberation, they commonly ignore fundamental prerequisites for this – that is the resolution of asymmetries in power, resources and trust among stakeholders*." (Healy, 2009[21] p. 1652).Inequalities have to be explicitly taken into account when designing a participation scenario, especially in the field of health care decision making where actors from very different backgrounds are involved. The ideal situation can be described as follows:

"*The notion that fair, free and open forms of debate and communication ensure that no one form of reasoning and/or knowledge dominates others (Habermas, 1984) amounts, in practice, to giving a representative range of stakeholders a seat at the table and facilitating unhindered and open forms of discussion and information exchange between them"* (Healy, 2009[21] p. 1646).

However, this approach ignores impediments, such as trust deficits and asymmetries of power and resources between stakeholder groups. From the Habermasian perspective it is assumed that these inequities simply dissipate by the facilitation of open, un-coerced communication.[60] However, this assumption has been debated a lot in the literature. Scholars such as Healy[21] assert that asymmetries in power and knowledge are not resolvable by means of communication exercises designed to even the gap between the 'haves' and the 'have-nots'.

A second way to address power inequalities is **to provide the participants with information.** At least in theory it has the potential to soften knowledge inequalities. However not everybody agrees with this viewpoint. Critics argue that providing participants with information does not eliminate knowledge (and hence power) inequalities, because information is not a synonym for knowledge. *"[...] information, in itself, is not knowledge, nor do we become any more knowledgeable through its accumulation. Our knowledgeability consists, rather, in the capacity to situate such information, and understand its meaning, within the context of a direct perceptual engagement with our environments*" (Ingold, 2000[61] p. 21). This point of view makes explicit the tension between lay and expert knowledge. Involving the public in health care decisions, means lay insights and expertise are included in decision making. Lay expertise stands in a very specific relation to expert knowledge. A number of authors strongly defend the value of lay expertise and so called tacit knowledge. For example: "*Instead of serving as knowledge repositories, local people actively create forms of understanding as they negotiate the conditions of everyday life*" (Irwin, 1999[62] p. 1322). Others, for example Healy[21] are more critical about how the tensions between lay and expert insights can be addressed in public participation exercises.

Finally, the ***direction of information flows*** is to be considered when talking about relations between actors (actors are everyone involved, also the researchers or initiators of the participation process). It is also linked to the intensity of participation. The direction of information flows can be:

1. one-way from the initiator to the public (to inform),
2. one-way from the public to the initiator (to consult), or
3. interaction between public and initiator (to discuss).

However, also among citizens/participants information exchange may take place. For example, in the case of a population survey, respondents do not meet, nor deliberate before answering the questions, while in focus groups they get the opportunity to discuss and exchange opinions. Hence, in the second case, citizens explicitly construct their opinion in interaction with others within the participation method chosen. Harrison and Mort[63] developed a four-fold typology (see Table 2) from the point of view of the lay person who gets involved:

1. uninformed without deliberation (e.g. population survey),
2. uninformed with deliberation (e.g. focus group),
3. informed without deliberation (e.g. referendum or population survey) and
4. informed with deliberation (e.g. citizen jury).

Table 2 – Methods of public and patient involvement situated on the axes of deliberation and information

Information Deliberation	To provide information	No information provided
Lay persons exchange ideas **Small non-representative group** **Convergence of ideas** **Taking the perspective of public policy**	e.g. citizen jury	e.g. focus group
No exchange of ideas **Large representative group** **Divergence of ideas** **Taking the perspective of health service user**	e.g. referendum	e.g. population survey

To provide lay persons with information and give them the opportunity to construct their opinion in interaction with others may seem the most complete strategy, but successful deliberation requires a small number of participants. However the advantages of deliberative processes should be weighed against the disadvantage of non-representativeness. Also with deliberative methods, opinions are more likely to converge, while with non-deliberative methods a greater variability in opinions can be expected[55].

Key points

- **Public and patient involvement is a complex concept which can be described in mainly four key-dimensions: (1) the level of participation, (2) the intensity of participation, (3) the type of actors in the participation process, and (4) the relationships between actors.**
- **The configuration of these dimensions, together with the aim of the participation initiative and the context attributes, are decisive in the selection of the participation method.**

3.7. The VALIDITY of public and patient involvement

Validity refers to the extent to which a concept, conclusion or measurement corresponds accurately to the real world. One of the validity issues regarding public and patient involvement is the grassroots dilemma.

By the mere fact of participating in health care decision making, citizens or patients may lose touch with the broader public they represent and become more alike other stakeholders in the decision-making process. So the question is whether participation transforms citizens and patients into a specific group with own interests, ideas, opinions, potentially different from the public they are supposed to represent. Moreover, participation in formal structures is not an easy task and many volunteers lack the knowledge necessary to be able to contribute.[64] Therefore, in the Netherlands for instance volunteers often receive training from their (patient) organisation to be able to understand medical and scientific knowledge, to develop negotiating skills, or to be able look beyond their own experiences. The professionalization of participants in health-care

decision-making raises questions about representativeness once they have different knowledge and abilities than the average citizen or patient.[64]

Abelson et al. (2003)[47] describe this dilemma as follows: "*There is the additional threat that as citizens become more informed about the health care system and are exposed to the harsh realities of making difficult and highly politicised health care decisions, they may lose their lay perspective and their views may become more closely aligned with those of the "professionals" (Mullen, 2000). A balance appears to be required between the development of an informed, engaged citizenry who can actively and effectively contribute to decision-making processes but who do not become co-opted (either formally or informally) by that process*." (Abelson et al., 2003[47] p. 247).

One potential way out of this dilemma lays in the complementarity between the scientific knowledge of health care professionals about what constitutes good health care on the one hand, and citizens knowledge about local needs and resources in relation to health. Stated differently it could be argued that citizens or patients should be valued for their own expertise and specific contribution, rather than expecting them to become technical experts or perform tasks requiring specialized knowledge.[65] Alternatively, one could also imagine situations in which health care professionals or service providers are less "capable" of making decisions and in which public and patient involvement could be very useful, for example, when it comes to policy decisions in which health professionals or service providers have a direct conflict of interest, e.g. because it concerns the funding of a health service they provide themselves.[65]

Key points

Involved citizens or patients may evolve to a specific group with own interests and ideas, potentially different from the public they are supposed to represent.

3.8. The EFFECTIVENESS of public and patient involvement

Key questions

What constitutes "successful" public and patient involvement in health care decisions?

Does public and patient involvement result in better health outcomes, compared to when the public is not involved in health care decision making?

How can (the effectiveness of) public and patient involvement be evaluated?

What are the criteria to assess the effectiveness of public and patient involvement?

Should we adopt a process oriented (participation as an end in itself) or outcome oriented approach (participation as means to an end)?

Does public and patient involvement in health care decisions lead to better decisions, higher quality of health care, a more sustainable health system and/or more equity?

3.8.1. Is public and patient involvement effective?

Evaluation of the quality of public and patient involvement should be inherent in involvement systems.[59] Public and patient involvement is about being able to change things.[20] In order to be meaningful, public and patients' views should have a direct impact on shaping health care activities and processes. However this as such cannot ensure service improvement.[59] The hierarchical conceptualisation of involvement assumes that the more power is transferred to the public, the higher the quality and quantity of involvement.[59] Studies evaluating the impact of public and patient involvement are often not clear about the nature of outcomes they aimed to measure in order to determine the effect of public involvement.[20]

The evaluation of public and patient involvement depends on the approach taken (see point 3.4). If participation in health care decisions is seen as an end in itself (*empowerment perspective*), it follows that decisions made through a participatory process are valuable and legitimate, because they

emanate from a participatory process which is valued in itself, regardless of the particular policy outcome. In this case, evaluation of the effectiveness of the participation involves a **process evaluation.** When participation is defined as a means to an end (*consequentialist perspective*), it should be evaluated according to whether it helps to achieve these goals, which is an empirical question.[1] It involves an **outcome evaluation**, where outcomes can vary between systems and can be multiple.

Question is hence, depending on the perspective taken and the defined goals, how well participatory processes of decision making lead to a more democratic way to decide, less technocratic and probably more humanist choices, more quality of (health) care, better health, equity of (health) care consumption, equity of the financing of health care, financial accessibility of (health) care, sustainability of the health care system, cultural accessibility of (health)care, safety of health care and, individual and collective responsibility.

The capacitating perspective is important in a context of limited public expenditures and of growing financial responsibility of the 'consumers' of public goods. Indeed, to be or to become responsible, the public and patients (or more generally, the consumer of public goods and services) have to be really 'free' to make choices for him and for the society. The freedom is not only a declarative right but also a concrete and implemented right. A 'free' citizen who understands the issues of a decision process and who participates to this process is also ready to accept a individual and collective responsibility.

There is a lack of research on the effectiveness of public and patient involvement.[1, 18, 25] There is no empirical evidence regarding which method is most effective under a variety of circumstances.[47, 53, 54] Central in this matter is the fit between the participation method and the context in which it is applied. In order to identify a successful match we surveyed stakeholders in the Belgian health care system as described in Chapter 1 of this report.

3.8.2. *How to measure effectiveness of public and patient involvement?*

The absence of research evidence on whether increased public and patient involvement leads to "better" health care decision suggests the difficulty of such an endeavour. We present possible evaluation criteria and tools for evaluation as discussed in literature.

Generally, a good fit is needed between the aim of the participation initiative, characteristics of the participation method and characteristics of the context in which the participation method is applied. Evaluation criteria mentioned in the literature are related to both the participation process and outcomes,[25] e.g., the improvement in health status [1].

Several evaluation frameworks or tools have been described.

Abelson et al.[47] (p. 244) identified four key components for the evaluation of deliberative processes (first three) and outcomes (fourth):

- **Representation**: this component concerns the legitimacy and fairness of the selection process. Representation is a difficult issue, because not only are there several types of representation, e.g. geographic, demographic or political[47], also the representation of shared characteristics does not necessarily translate into accurate representation on the level of expressed opinions.[66] Some authors argue that "*it is not representation of individuals that is important, but representation of the range of discursive positions within society*." (Dryzek, 2001[67], cited by: Martin, 2007[66], p. 37). One of the critiques regarding public and patient involvement is that, as Martin states, "*participation initiatives are seen to represent some subgroups of the public better than others.*" (Martin, 2008[66] p. 37). On the other hand, no participation means that no subgroups are represented.
- **Procedural rules**: the extent to which the procedural aspects of a consultation process are legitimate, reasonable, responsive and fair. This translates to questions such as: At what point in the decision-making process citizens' input has been sought? Did participants have the opportunity to challenge the information presented? Who is listening?

- The **information used** in the process: This criterion relates to what and how information is selected, presented and interpreted. What is the quality of the information participants receive, but also provided by participants. There is an "unavoidable power imbalance between those who possess what seems to be the desired information, who control its dissemination and the forum within which it is debated(…), and those who do not. "*The vast majority of the public will defer to the 'experts' when it comes to these decisions because they may not have the expertise required to critically appraise the information presented*." (Abelson et al., 2003[47] p. 246). Inability to judge the adequacy and quality of the information presented implies a risk of being easily influenced, intentionally or unintentionally) by jury sponsors, organisers or other involved parties[47]. In addition, power imbalances may also exist among the participants themselves.
- **Outcomes/decisions** arising from the process: this set of evaluation principles considers the various potential outcomes of the participation process. For example, the extent to which public input was incorporated into the final decisions, of if better decisions were taken and the participation process improved policy making. "The limited experiences with deliberative methods in the health sector, to date, have demonstrated that the outcomes of deliberations are rarely, if ever, binding and are often heavily "managed" by the sponsoring organisation, typically the health authority." (Abelson et al., 2003[47] p. 247).

Another evaluation tool is designed by the IAP2. They developed the *"IAP2 Core Values for Public Participation"* for use in the development and implementation of public participation processes. *"These core values were developed over a two year period with broad international input to identify those aspects of public participation which cross national, cultural, and religious boundaries. The purpose of these core values is to help make better decisions which reflect the interests and concerns of potentially affected people and entities*." (http://www.iap2.org/displaycommon.cfm?an=4, 24/02/2012). In order to maximize effectiveness, the following IAP2 guidelines, which could also serve as a basis for defining process indicators for the evaluation of citizen and patient involvement initiatives, seem useful:

Public participation:

- is based on the belief that those who are affected by a decision have a right to be involved in the decision-making process.
- includes the promise that the public's contribution will influence the decision.
- promotes sustainable decisions by recognizing and communicating the needs and interests of all participants, including decision makers.
- seeks out and facilitates the involvement of those potentially affected by or interested in a decision.
- seeks input from participants in designing how they participate.
- provides participants with the information they need to participate in a meaningful way.
- communicates to participants how their input affected the decision.

These core values have, however, been severely criticized by Healy[21] for that these 'core values' do not recognize that the public may in addition to requiring 'information', might have some 'information' to contribute. She adds that "*rather than empowering the public such an approach is more, […], about legitimating conventional expert-determined decisions and the status quo they reflect*." (Healy, 2005[21] p. 1653).

In order to take the public seriously, Healy[21] states that the frameworks and guidelines informing the design and the conduct of public participation exercises should ensure that due weight and consideration are given to public knowledge and. In other words public insights and understandings should be treated as of equal value as expert knowledge. By consequence expert knowledge should be open to public criticism, in the same way as lay knowledge is criticized by experts.

Two final difficulties for the evaluation of public and patient involvement initiatives should be mentioned: (1) because participation is a process, it is difficult to know when it has reached its endpoint or when it should be evaluated, (2) even in successful participation projects there is no guarantee that what worked in one situation will work in another, or will work in the future.[27] However, even if the evaluation seems to have limitations, the situation in terms of procedures or attained goals with participation has to be compared with a situation without participation, not necessarily with an 'ideal' situation, whatever that might be.

Key points

- **A good fit is needed between the aim of the participation initiative, the participation method and the context in which the participation method is applied.**
- **Evaluation criteria mentioned in the literature are related to both the participation process (e.g. representation, procedural rules and information) and outcomes (e.g. better decisions).**
- **The evaluation of the efficacy of public and patient involvement encounters a number of difficulties, such as the timing of the evaluation and the transferability or generalisability of the conclusions.**
- **However, even if the evaluation seems to have limitations, the situation in terms of procedures or attained goals with participation has to be compared with a situation without participation.**

3.9. Weaknesses in the public and patient involvement literature

Key questions

What are the weaknesses in the participation literature?

How can we close these gaps by means of the planned Delphi rounds?

Weaknesses identified in the literature concerning public and patient involvement in health care decision-making processes are:

- There is a lack of **comparative research** (comparing several participation methods).
- There is a lack of **evaluation research** (evaluating participation methods): "While there have been determined efforts to improve the rigour of public participation evaluation, most evaluations still fail to provide decision makers with the research evidence they need to inform subsequent public involvement processes." (Abelson et al., 2007, p. 2116).
- The terminology to describe and categorize public involvement methods and the contexts in which they are implemented are imprecise and inconsistent.[68] "*We still know very little about what does and does not work when it comes to designing public involvement processes*." (Abelson et al., 2007[52] p. 2116).
- Little is known about how public participation processes are shaped and constructed by the different contexts within which they are implemented.[52]

3.10. Conclusions from the literature

Regarding which method to use for public and patient involvement, we concluded from the literature[24,69] that the best way of engaging the public in priority setting is to use multiple participation methods, to engage multiple publics, and to use a combination of methods with different levels of intensity, in order to get a more rounded and nuanced understanding of the public's desires. In addition to face-to-face interactions and on-going initiatives are preferable instead of distant or single exercises.

We should be aware that different methods might produce different impressions of the public's preferences. Hence there is a need for systematic comparisons and evaluation studies. Moreover evaluation studies should not be restricted to outcome evaluation, but also involve process evaluation.

In order to be successful public and patient involvement needs to be properly implemented with careful consideration of the context.

4. DELPHI PANEL

4.1. Aim of the Delphi panel

The purpose of the Delphi survey is to understand the acceptability of different ways and methods to involve patients and citizens in health care decision-making in a Belgian context and to identify points of convergence and divergence among the participants. Eventually, we aim to make, based on the results of this survey, realistic recommendations with respect to public and patient involvement initiatives in the Belgian health care context.

4.2. Methods of the Delphi survey

Participants were consulted in two "rounds". In the first round, respondents are asked to fill out a questionnaire that was developed based on findings from the literature review and preparatory interviews with some stakeholders. For the second the responses on the first questionnaire were used to develop a second questionnaire. The second questionnaire is built on consensus reached in the first questionnaire and explored further consensus on points where no consensus was reached. As the main objective was to examine the overall acceptability of citizen and patient involvement to stakeholders, rather than to study potential conflicting views of different stakeholder groups, the focus was on items for which consensus was reached, rather than on item for which conflicting responses were observed. Nevertheless, all responses are reported, both those for which consensus was reached and those for which no consensus was reached.

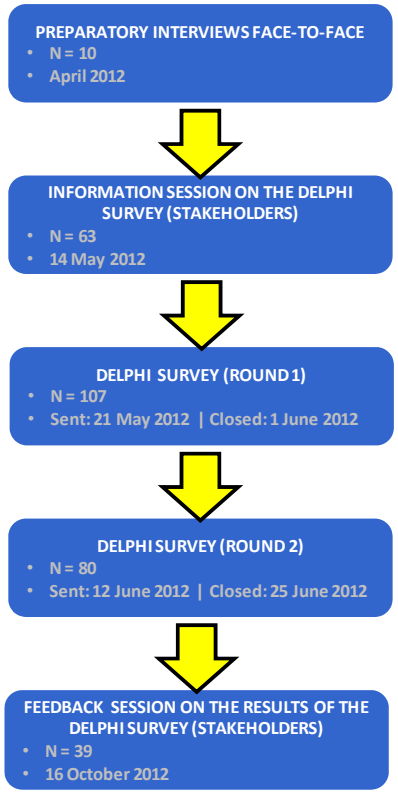
The main advantages of the Delphi methodology are the capacity to collect opinions from a distance in an anonymous way, avoiding direct confrontation, quick identification of consensus on complex matters and to avoid the excessive influence of one specific group, which might occur in a face-to-face approach.

The main limitations are linked to the speed, which leaves little time between the rounds and the length and complexity of the questionnaire, which has to be kept in balance to keep a high response rate.

There are no universal guidelines regarding the Delphi technique. Nevertheless several subtypes are identified. In this research project we combined elements from the modified Delphi, with elements from the policy Delphi. In a classical Delphi the first round is used to facilitated idea generation, this is also the case in a modified Delphi, but the modification consists of the form the first round takes. The first postal round is replaced by face-to-face interviews to explore the scene (see 4.2.1). In a policy Delphi participants are as is the case here, experts or stakeholder groups, who are surveyed to come to consensus and agree future policy on a given topic.[70]

Since quantitative data collection tools, such as questionnaires or scales, and quantitative analysis strategies, are (or can be) integrated in a Delphi survey, it is not a pure qualitative research method. Nevertheless, the main aim here was to give a large number of participants the opportunity to express their opinion about public and patient involvement in Belgian health care decisions anonymously. Although representativeness in a statistical way is not aimed at, theoretical representativeness is important. This means that the variety of positions in the field or opinions regarding the subject should be covered.[71] Therefore participants need to be carefully chosen because of their expertise, experience or knowledge in the field of the research question. These methodological considerations resulted in a rather big sample as mentioned above, the sample is well balanced as experts from all types of background (read stakeholder groups) are included.

Globally, the following four main consecutive steps were performed:



4.2.1. Preparatory Interviews

4.2.1.1. Aim

The study started with ten face-to-face semi-directive interviews with a small sample of 10 stakeholders. The objective of these interviews was to prepare the Delphi questionnaire for the first round, and more specifically:

- To understand the general attitude of stakeholders with regard to public and patient involvement
- To identify potential items, models and eventually scenarios to be included in the Delphi
- To learn about past experiences with public and patient involvement in Belgium
- To get a first general impression of the acceptability of models and scenarios
- To generate a general understanding of the context, so as to be able to tailor the questioning to this context

4.2.1.2. Participants

Interviewees were a mix of all types of stakeholders: politicians, civil servants, representatives of the medical professions and care institutions, patient organisations and sickness funds. Nearly all interviewees are active in RIZIV – INAMI organs.

The initial list of potential interviewees was based on persons playing a role in decision making today, i.e. secretaries and presidents of decision-making bodies, who are expected to have a general view on the concerns and sensitivities of stakeholders represented in the decision-making bodies. This led to a list of seven persons covering all stakeholders except the scientific community and politicians. Three persons were added to this list to cover the political dimension (again chosen among persons in the RIZIV – INAMI organs), science and a member of the advisory committee on bio-ethics as an independent expert, bringing the total number of interviewees to 10.

4.2.1.3. Data collection tool

The interviews were based on the interview guide that is included in Appendix 3.1.

The interview guide encompassed topics considered for the first round of the Delphi. It was developed in collaboration with all study team members. There was no piloting, but immediate exchange within the research team after the first interview, and a mid-term exchange when five of the ten interviews had been done.

4.2.1.4. Data collection

Interviews were all conducted face-to-face in the second half of April and early May 2012. They lasted between 1 hour and 1.5 hours. The location was chosen by the interviewee. Notes were taken, interviews were not taped. There is no specific report on the interviews as they were mainly meant to help develop the first round questionnaire.

4.2.2. Information session

4.2.2.1. Aim

The objectives of the information session were:

- To motivate people to participate in the Delphi
- To inform participants about the study and Delphi process and how this would work in practice
- To improve the knowledge of potential participants on the topic by presenting the results of the literature review
- To collect questions and suggestions with regard to the study

4.2.2.2. Participants

All stakeholders invited to participate in the Delphi survey (see 4.2.3.1) were invited to attend an information session. Finally, 63 persons participated.

4.2.2.3. Content

The information session was organised on 14 May 2012 in Brussels.

Topics covered in the information session were: the objectives of the project, the results of the literature review, the steps in the Delphi process and how this would work in practice. The full programme is available in Appendix 1.

The exchanges were essentially informative, except one, on the importance to involve also participants from regions and communities, given the expectation that in the near future more of the health care policy making and implementation would move from the federal to the regional/community level. This led to a decision to expand the list of potential participants to include civil servants and policy makers at the regional and community level.

4.2.3. Delphi Rounds

4.2.3.1. Participants

Participants invited to the Delphi panel are expected to be experts on the subject. In this case, the subject is defined as the decision-making process for reimbursement decisions in the context of the Belgian health care system. Were therefore invited:

- Politicians, i.e. all members of the federal parliament
- High-level civil servants and policy makers at national/regional/community level
- All members of the decision-making organs, i.e. civil servants, representatives of sickness funds, representative organisations of the "supply side" (medical professions, care organisations, pharmaceutical companies, manufacturers of medical devices, organisations who actually finance the system (employer organisation and trade unions).
- Consumer associations and patient organisations representatives based on a nominative lists of persons who expressed their interest in the subject, e.g., by participating to events (for patient organisations), or by direct contact (for consumer organisations)

In total nearly 600 persons were invited to participate in the first round. More than half were members of the parliament.

4.2.3.2. Data collection tools

First round questionnaire

The questionnaire was developed based on the literature review, the preparatory interviews and the comments received during the information session. It was structured in four parts, in addition to a part covering the profile of the respondent:

- Part I : General opinion with regard to public and patient involvement
- Part II : Perceived benefits and risks of public and patient involvement
- Part III : Preferences with regard to the intensity of public and patient involvement
- Part IV : Preferences with regard to modalities of public and patient involvement

A background document was accompanying the questionnaire. This background document is included in Appendix 3. It is based on the first results of the literature review and covers the various parts of the questionnaire. It was kept brief to ensure that participants would effectively read the document before answering the questionnaire. The questionnaire is included in Appendix 3.2.

Two major principles were adopted during both the first and the second round:

- The responses remained **anonymous** for the KCE and for the other participants. The results are transmitted by the research team without any reference to the individual participants. Final results are globalised and integrated in the KCE report.
- Participants were asked to answer the questions based on their **personal opinion**, and not as a representative of an organisation (their employer or the organisation they might represent).

Second round questionnaire

The purpose of the second questionnaire was to explore further potential consensus on pertinent proposals. These proposals were going a step further than what was included in the first round questionnaire as to built on the consensus already reached based on the first round results (see criteria in section 4.2.3.4).

A major part of the second questionnaire (see appendix 3.3) consisted of a reconsideration of the items in the first questionnaire that did not reach consensus. The questioning was simplified and consisted of a yes/no answer for most items.

New items suggested by respondents in the first questionnaire, were added if at least two participants suggested the item.

In addition, the second questionnaire asked questions about concrete models and scenarios for public and patient involvement as well as about who would best represent the public and patients, based on the results and consensus reached in the first round.

In addition to the 2nd round questionnaire, participants received:

- A synthesis of (confidential) results from the first round (as part of the questionnaire): the synthesis mentions the topics, items or proposals on which a consensus was reached in the first round.
- A description of the sample of participants to the first round (in a separate document).

4.2.3.3. Running the data collection

All questionnaires were sent out by e-mail on 21 May 2012 together with the background document. Participants were asked to return the questionnaire by 1 June. A reminder was sent a few days before the deadline.

Participants to the first round received a second questionnaire on 12 June 2012. They were asked to send their responses by 25 June. A reminder was sent a few days before the deadline. An extended deadline of one week was given to increase the final response rate.

4.2.3.4. Analysis

For the first round, consensus was defined as at least 65% agreement/importance among the participants and a maximum of 15% disagreement/unimportance. Response categories “very important” and “important” were taken together to determine the percentage of importance, as were response categories “Fully agree” and “agree” to determine the percentage of agreement. The same applies to “not important” and “not important at all” and to “not agree” and “not agree at all”. The same consensus rule was applied for questions with only two response options (yes/no). In case of questions where respondents had to give their opinion as to what they consider to be “the most important”, a consensus was reached if 65% of the respondents chose a specific response as the most important. These cut-off points are arbitrary as there is no scientific basis upon which to base a threshold value for consensus.

For the second round, a binary answer (yes/no) was used, and consensus was again arbitrarily defined as an approval rate ≥65%.

The present report is based on responses to both rounds. Some quotations issued from the comments expressed during the survey are used to illustrate the results or deepen understanding.

Although results are often presented as percentages, the reader should be aware that these results are mainly qualitative (see 4.2). No statistical analyses were performed. The use of percentages in the presentation of results is to express the consensus reached by the group of experts who participate in the survey and has no ambition to be statistically representative.

4.3. Results of the Delphi survey

4.3.1. Description of participants

One hundred and seven (107) respondents returned the first and 80 respondents the second questionnaire. All stakeholder categories were represented in the sample (Table 3[e]).

The majority of the participants are currently active as full members or as replacements in the organs of RIZIV – INAMI where reimbursement decisions are prepared or taken. This is particularly the case for sickness funds, medical professions or care institutions and academic representatives (see Table 1 in appendix 4).

[e] Note that not all respondents filled out all descriptive items in the questionnaire, explaining the difference between the total number of respondents and the number of respondents per item.

Table 3 – Description of the participants to the Delphi survey

		Round 1 (%)	Round 2 (%)
Sex		**N=107**	**N=80**
	Male	57.0	55.0
	Female	43.0	45;0
Age		**N=103**	**N=78**
	< 25 years	0.0	0;0
	25 – 35 years	4,9	2.6
	36 – 45 years	17.5	19.2
	46 – 55 years	35.0	35.9
	56 – 65 years	33.0	34.6
	> 65 years	9.7	7.7
Educational background	***(multiple answers possible)***	**N=103**	**N=78**
	Law	11.7	10.3
	Economy	9.7	9.0
	Nursing	6.8	3.8
	Pharmacy	8.7	10.3
	Medical	35.9	38.5
	Other	28.2	28.2
Stakeholder category	***(multiple answers possible)***	**N=107**	**N=80**
	Politicians, members of cabinets	13.1	10.0
	Patient organisations	26.1	21.3
	Sickness funds	27.1	22.5
	Federal, regional or community institutions	15.9	20.0
	Representatives of medical professions or care institutions	27.1	27.5
	Organisations from the associative world*	10.3	7.5

		Round 1 (%)	Round 2 (%)
	University / Research	15.0	15.0
	Other	8.4	11.3
Membership of decision-making organs RIZIV - INAMI		**N=105**	**N=80**
	Active member (full members or replacement)	57.1	53.7
	Former members	5.7	3.7
	Never been members	37.1	42.5

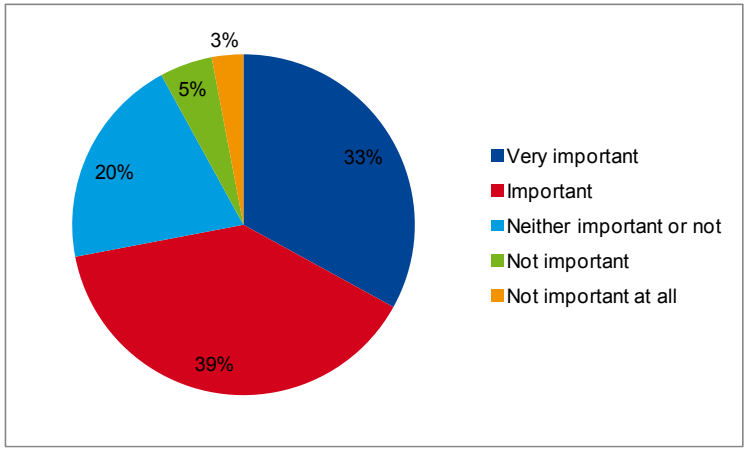
** Under this heading are grouped organisations from civil society that are membership based and not directly linked to the health sector. These are mainly the employer and employee representative organisations.*

Sixty eight participants out of the 107 to the first round consider they have a former experience with public and patient involvement. The majority (48) considered this experience as positive, while 5 consider it as negative. Twelve respondents have experienced the participation as neither positive nor negative. Three respondents did not answer this question.

4.3.2. *Global point of view of the participants on the importance of patient-citizen participation*

Globally, there is a positive attitude as to more participation of both the citizen and/or the patient in the decision-making process for health care reimbursement. Indeed, a large consensus[f] has been reached on this point during the first round since 72% of the respondents consider public and patient involvement as (very) important and only 8% as not important or not important at all. The 8 respondents considering that public and patient involvement is not important or not important at all are not concentrated in one category of stakeholders but are spread across all categories of stakeholders.

Figure 4 – Importance of public and patient involvement in decision-making (N=107)



This high level of importance and of interest for the subject can be illustrated by comments made by the participants to the first round :

« Gaat over gezondheid = hoogste goed, burger-patiënt biedt een ander, verrijkend gezichtspunt wat zeker zal leiden tot 'betere' beslissingen, beter afgestemd op de realiteit van patiënten, draagt bij tot een betere bewustwording bij patiënt burger en meer begrip voor realiteit dat er soms moeilijke keuzes moeten gemaakt worden. »

« Le citoyen patient est le premier concerné par le coût des soins de santé. S'il est patient, il connaît l'impact de sa maladie sur son budget et peut faire part de ses difficultés. Il peut aussi être le témoin de l'efficacité d'un traitement. En tant que citoyen, il doit en outre être conscient du coût des soins de santé dans le budget global de la sécurité sociale et de la pertinence des choix à opérer quant à l'allocation des ressources. »

« Het gaat om beslissingen die de burger aanbelangen. Zijn input kan tot betere beslissingen leiden. »

[f] The items considered to have reached a consensus during the first round are those with 65% or more of "approval" and 15% maximum of "disapproval."

« C'est le premier concerné par les soins de santé: il faut encourager la prise de conscience des futurs patients sur les décisions qui le concerneront directement ».

The following citation comes from a participant who answered « neither important, nor not important ». It synthesizes the motivations, and challenges associated with public and patient involvement:

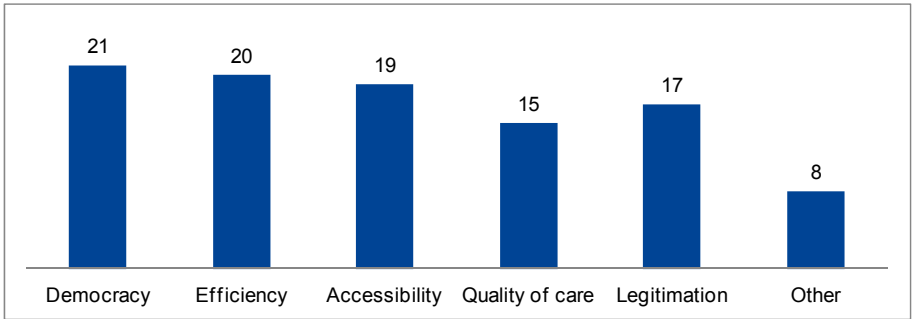
«Uiteindelijk gaat het om beslissingen die de burger-patiënt treffen. Een participatie aan deze beslissingen zal een beter begrip doen ontstaan voor de beslissingen die genomen worden waardoor er uiteindelijk minder weerstand ontstaat. De complexiteit van deze beslissingen vormt een uitdaging om dit met de burger-patiënt te bespreken op een bevattelijke manier. Een advies bij het stellen van prioriteiten bij beperkte middelen lijkt mij één van de meest waardevolle redenen waarom burger-patiënten zouden kunnen betrokken worden, naast het bewaren van een gelijkwaardige toegankelijkheid van zorgen en middelen. »

The reasons why it is important to involve citizens and patients in the decision-making are quite diverse (see Table 3 in appendix 4): there is consensus among the participants about to do it in the name of democracy (67%), to guarantee the efficiency of the health care system (82%), to increase quality of care (82%), to increase transparency in decision-making (87%), to increase awareness of costs (80%), to guarantee accessibility to health care for all (73.9%), to legitimate the decisions (77.6%), to empower (73.9%) and to responsabilize (76.4%) patients. The only proposed item that has not reached consensus is that the involvement of citizens and patients has to be done in order to render the health care system more demand-driven (54%).

Even if a (high) level of consensus was reached for these specific motivations, no clear "common vision" appears from the various types of stakeholders or participants. As shown in Figure 5, highlighting the most important motivation for public and patient involvement according to the respondents, none of the motivations dominates, even not within respondents coming from a same stakeholder group. There is also no significant difference between respondents who are current or past members of the decision-making organs of RIZIV – INAMI and those who are not, except for accessibility, which is more often considered as the most important objective by those who are or have been in the decision-making bodies.

Quality of care is slightly less than the other reasons mentioned as a motivation to involve citizens and patients in decisions. This may be due to the fact that the respondents may feel that the potential impact of citizen and patient involvement on quality of care is probably limited.

Figure 5 – Motivation identified as the most important to involve the citizens and patients in decisions (%) – N=96



4.3.3. Benefits and risks

4.3.3.1. Benefits of public and patient involvement in the decision-making process for reimbursement of health care products

A large consensus appears on the benefits of public and patient involvement in the decision-making process for reimbursement of health care products (92%), already in the first round.

The consensually considered important or very important benefits are (see Table 4 in appendices for more details):

- the possibility to take into account the needs and priorities as experienced by the citizens and patients (76%),
- the introduction of the quality of life dimension in addition to the therapeutic and diagnostic dimensions (69%),
- the responsibilisation through a better awareness about challenges and costs (69%),
- the expertise acquired through experience (67%),
- the broadening of the reflection to cover more than the purely financial dimension (66%),
- the possibility to take into account in the decision-making process of the elements that are not being reimbursed but do play a role for citizens and patients (88%),
- the creation of a better balance and allocation between the different alternatives in the context of limited resources (70%).

The three first benefits on the list are also considered by the participants as the three most important ones.

There is no consensus on the following potential advantages of public and patient involvement: the possibility to develop a counterweight for the traditional lobbies and decision-makers (60%), the possibility to get approval of potentially unpopular decisions (49%), and the possibility to take into account the diagnostic and therapeutic dimensions as reported by the patient (59%).

4.3.3.2. Risks of public and patient involvement in the decision-making process for reimbursement of health care products

Participants are conscious of the existence of risks (85%) related to public and patient involvement in reimbursement decisions.

The risks considered to be (very) important according to the participants are (see also Table 5 in appendix for details):

- the difficulty of an adequate representation to express a collective opinion (72%),
- the difficulty of access to the necessary means (human, financial …) to participate effectively (68%),
- the lobbying or power games of other stakeholders (76%),
- the risk for patients to be instrumentalised and used as an alibi (71%),
- the risk of subjectivity (66%).

In addition, the majority of respondents (68%) believes there is a risk that rare diseases would receive less attention.

The five risks having reached consensus are also selected most often in the top 3 of the most important risks of public and patient involvement in the decision-making process for reimbursement of health care products.

For several risks no consensus was reached, while the proportion of respondents who consider them as (very) important are still near to or up to 50%. These risks were the utilization of the patient by industry (63%), the diversity and multiplication of existing representations for different diseases (59%), the risk that more attention will be done to the personal benefits than to the common good (59%), the domination of protest aspects (protest voice) (51%), the diversity and multiplication of existing representations on a geographical level (national, regional, local...) (50%), and the risk of slowing down the decision-making process (46%).

4.3.3.3. Ratio benefits/risks

Considering all benefits and risks, participants reached a consensus in the first round on the fact that benefits outweigh the risks (67%), 18% consider they are equal to the risks and 15% consider the risks are superior to the benefits. Only one of the respondents who considers the risks outweigh the benefits has no experience as a member of the decision-making organs of RIZIV – INAMI, the others are all current or past members of the decision-making organs. This suggests a higher degree of conservatism and risk avoidance among those who are today part of the decision-making process.

More precisely, they agree on the fact that public and patient involvement in reimbursement decisions has important advantages, even if it is also associated with clearly identifiable risks. These statements are illustrated by the following comments of participants:

> *« Une fois qu'on a bien cerné ou étaient les risques, il n'y a qu'à se fixer des moyens et des objectifs clairs pour les éviter et les bénéfices suivront »*
>
> *« De voordelen kunnen de risico's overstijgen maar dit vraagt uiteraard dat de nodige inspanningen gedaan worden om de risico's te verhelpen ».*
>
> *« Les risques peuvent être identifiés et appréhendés. Ils ne doivent pas occulter le bénéfice d'une participation responsable ».*
>
> *« De voordelen van participatie wegen op tegen de nadelen indien de juiste randvoorwaarden worden gerespecteerd (vb.: professionalisering van patiëntenorganisaties) ».*

4.3.4. Representation model of citizens and patients

Different models of involvement or representation of the public and patients were proposed :

- The « citizen » model : one person, not directly concerned by a specific disease – this means an « average » citizen, is involved. This person would generally differ for different consultations.
- The « citizen-representative » model : an organisation sends a « representative » having the legitimacy to speak on behalf of the citizens in general or of a group of citizens.
- The « patient-representative » model: (patient) organisations delegate a representative who can be a member of the organisation (directly involved as a patient or parent) or a staff member.
- The « patient » model : a member or not of an association, but participating as an individual patient, not as a representative.

A consensus appeared from the first round that the public and patients are best represented by a **representative of the citizen for strategic decisions** (68% chose for the "citizen-representative" model), and by a **representative of the patient for more operational decisions** (e.g. linked to a specific disease) (70% chose for the "patient representative" model).

The number of participants who do not want any public and patient involvement is very low: 4% for strategic decisions and 5% for operational decisions (see also Table 6 in appendix).

4.3.5. Level of public and patient involvement

Different levels of public and patient involvement were assessed by participants for three types of decisions:

1. the setting of global priority setting for the use of available funds.
2. decisions on the reimbursement of acts linked to a specific disease or treatment.
3. decisions linked to the reimbursement of health care products for an individual patient.

This was covered for both patient and citizen in the first round, and more focused in the second round were public involvement was considered for the setting of global priorities, and patient involvement for reimbursement decisions for a specific act. This is in line to the consensus that appeared above.

The third type of decision was explored further in the second round, to check the absence of consensus.

Consensus levels identified are:

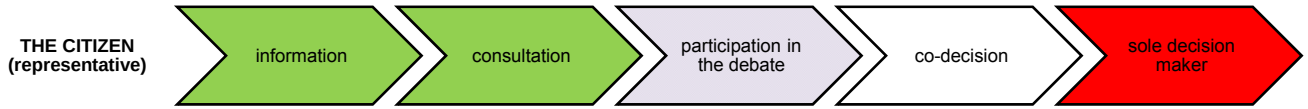
- for setting global budgetary priorities in health care, the **citizens** should at least be informed and consulted;
- for decisions about the reimbursement of particular products, the **patients** should at least be informed and consulted;
- for decisions related to the reimbursement of health care products for a particular patient, there was no consensus on (public or) patient involvement

As shown in Figure 5, the participants also agree on the fact that the public and patients representative should never decide alone for all these types of decisions.

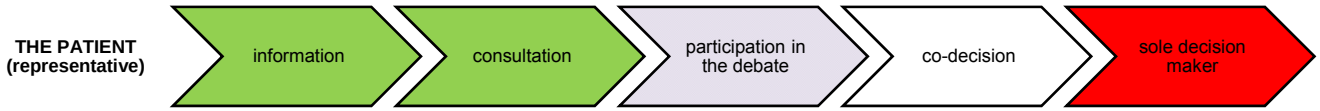
In the case of reimbursement of health care products for an individual patient, there is no consensus on the involvement or not of a representative of the patients. As could be expected, the persons who are not members of the decision-making organs of RIZIV – INAMI tend to agree with higher levels of involvement of the citizen or the patient. For the first type of decision the level of opposition for co-decision of the citizen is 66 % for the members, and is 36 % for the non-members. For the second decision the difference is less strong, but there is still significant difference: for co-decision of patients again, the opposition is 70 % among members and just below 45 % for non-members.

Figure 6 – Acceptable and non-acceptable levels of involvement

1. **To set global priorities for the use of available funds**



2. **To decide on the reimbursement of acts linked to a specific disease or treatment**



3. **To decide on the reimbursement for an individual patient**



Dark green: consensus on acceptance as a minimum level of involvement
Grey: accepted level of involvement but no consensus as to whether this should be the minimum nor the maximum level
White: no consensus
Red: consensus on rejection
Based on Table 7, Table 8, Table 9, Table 10, Table 11 in appendix 4.

4.3.6. Types of operational decisions

The potential field of operational application of public and patient involvement or participation appears to be quite large. Consensus was reached on a variety of potential decisions (see Table 12 in appendix 4), e.g. medications with a high cost and a high therapeutic added value (77%) and medications whatever the consumption volume (high: 66%; low: 76%). Are also retained as relevant: diagnostic high technologies (78%), invasive medical devices (82%) as well as products and therapies today at the charge of the patient (87%).

All other proposals did not find consensus amongst the Delphi panel, i.e. reimbursement of medication with high therapeutic added value but low cost per unit, medication with low therapeutic value and low cost per unit, reimbursement of non-invasive medical devices, of general medical products or alternative medicine. In summary, decisions that have a perceived low health or economic impact.

4.3.7. Modalities of participation

It appears from the results (see Table 13 in appendix 4) that for an effective participation it is better **not to limit participation to one method only** (69%). In addition, **utilizing different groups** to represent the patient according to the theme treated is better than always using the same group of patient representatives (84%)

It is important that participants can **exchange face-to-face their opinions before deciding** (78%). And for reimbursement decisions **for a new medication**, it is better that this interaction occurs **with the (representative of the) citizens and patients** rather than from a distance with a larger group of citizens and patients (77%).

Citizens and patients should be **involved only at milestones** and should **not necessarily be part of all deliberations** (80%).

Participants reject consensually that oral participation is enough and does not have to be combined with written participation (only 33% agree with this statement). They also disagree with the statement that involving the citizens and patients in reimbursement decisions is impossible without providing information in advance (85%): it means that involving the public and patients is possible for them without providing information in advance.

4.3.8. Success factors of public and patient involvement

All the success factors suggested in the Delphi questionnaire have reached a consensus, most of them already in the first round (see Table 14 in appendix 4). This illustrates the opinion of participants that public and patient involvement is not necessarily easy and that there are conditions for success:

- In terms of training:
  - the citizen, in order to contribute effectively to the decisions (71%);
  - all the stakeholders, because of this new approach and this new way of working (66%);
- In terms of operationalization:
  - In general:
    - Guaranteeing transparency (90%);
    - Select with caution the persons who are participating (89%);
    - Develop a legal base (66%);
    - Define a code of conduct for the individual persons participating (71%);
    - Define a code of conduct for the associations participating (74%).
  - Regarding the patients associations:
    - Organise a formal recognition of associations (65%);
    - Provide the patient associations the necessary budgetary and human means needed to deliver professional dossiers (77%)
- In terms of culture by creating a real participation culture (71%);
  - Obtain the constructive support of all stakeholders (65%[g]);

[g] This proposal reached then 64.7% of the votes. Because we have analyzed the first round without using decimal, it was considered as 65% and in consequence, it was not submitted for reconsideration in the second round. According to the very close proximity of the threshold to consider that a consensus does exist, we have considered that there is a consensus on this

4.3.9. Scenarios for public and patient involvement

Based on the consensus on public and patient involvement at the levels of « information » and « consultation » reached in the first round (see above), we created and tested more concrete participation scenarios during the second round. This was done using a simple decision tree for two types of decision and separately for citizen and patient participation.

For each of the four decision trees proposed, an optimal scenario appears which is indicated in blue in the charts on the next pages.

There is no consensus as defined for the other questions in the survey because for each characteristic of a scenario, respondents can chose between two or three options. The number of combinations then becomes very large, as a consequence of which it becomes difficult to reach a consensus as defined for the other questions (i.e. >65% of the respondents giving a particular response).

4.3.9.1. The optimal scenarios for informing

The optimal scenario for **informing the citizen on setting global priorities for the allocation of public health care resources** consists in informing the citizen from inside the existing organs (66%), at each step of the decision-making process (73%), by involving more than one representative of the citizen (87.5%) (Figure 7).

Still one third of the participants (34%) expressed a preference for information outside the existing organs. Information should be provided before the decision is taken for 52% (of these 34%) of them and after the decision has been taken for 48% of them.

The optimal scenario for **informing the patient with regard to decisions related to reimbursement of products linked to a specific treatment** is similar to the previous one but (Figure 8) presents a higher number of respondents choosing “inside the organs” and “at each step”.

Only 26% would choose to inform the patient outside the existing organs, and with a stronger preference on informing after the decision is taken.

In the first scenario, there is no significant difference between the respondents with regard to the choice of the place where the information is given (inside or outside the existing decision-making organs) according their current/past membership (or not) of the INAMI – RIZIV organs. In the second one, both groups are in favour of giving the information “inside” the existing decision-making organs”, but this is overwhelmingly so for those who are not in the INAMI – RIZIV organs today (90% against 63%).

In both scenarios:

- For participants preferring that the information is given “inside” the organs, the option to inform “at each step of the decision-making process” is preferred by respondents who are not members of the INAMI/RIZIV organs (respectively, 90% and 93% against 60% and 70%). On the option “one or more representatives”, the difference is too small to be significant.
- Respondents who are not members of the INAMI/RIZIV organs and who choose the option “outside the organs”, are much more in favour of informing the citizen before the decision than after the decision.

point. The percentage should probably have been higher if the proposal was asked in the second round.

Figure 7 – Model chosen to INFORM the CITIZEN with regard to setting global priorities for resource use allocation in health care

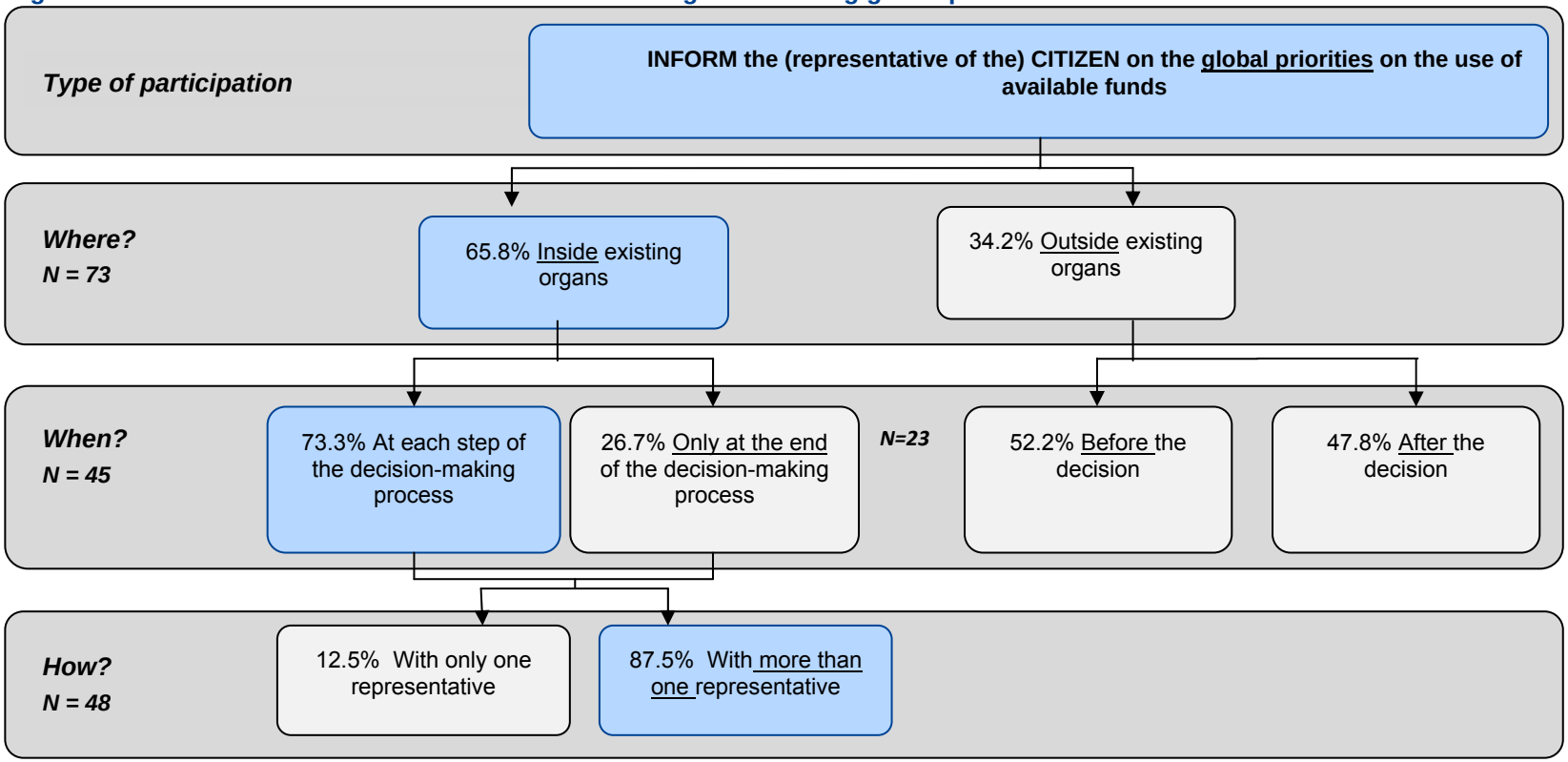
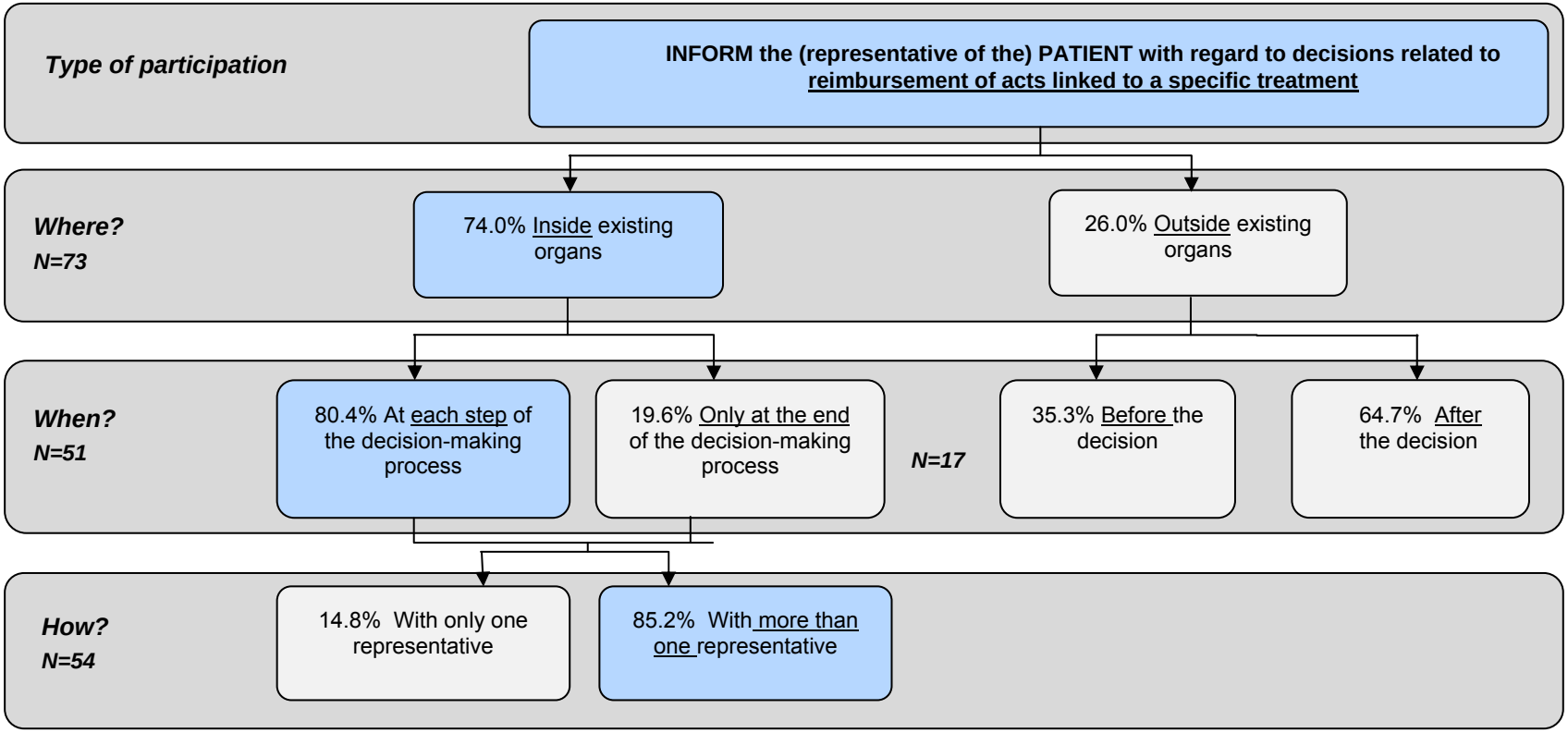


Figure 8 – Model chosen to INFORM the PATIENT with regard to decisions related to reimbursement of acts linked to a specific treatment



4.3.9.2. The optimal scenario to consult

The optimal scenario for **consulting the citizen on setting global priorities for the use of available funds in health care consists** in consulting the citizen inside the existing organs (53%), at each step of the decision-making process (70%), by involving more than one representative of the citizen (90%) (Figure 8). The majority of the respondents (61%) feels that the final decision should be motivated if it differs from the advice of the citizen.

The optimal scenario for **consulting the patient with regard to decisions related to the reimbursement of products linked to a specific treatment** is similar to the precedent one but (Figure 10) but scores are higher on the two first modalities, i.e. “inside the organs” and “at each step in the process”.

Here again, there is no significant difference in the choice related to the ‘place’ of the consultation between the group of current or past members of INAMI – RIZIV organs and the group of non-members for both scenarios. However, they do show differences in their preferred option for the timing of consultation and the impact of the participation:

- For participants preferring that the consultation occurs “inside” the organs, the option to inform “at each step of the decision-making process” is preferred by respondents who are not members of the INAMI – RIZIV organs (respectively, 81% and 95% against 64% and 67%). On the option “one or more representatives”, the difference is too small to be significant.
- For participants preferring that the consultation occurs “outside” the organs, although the sample is small, respondents who are not members of the INAMI/RIZIV organs are more in favour of permanent rather than one-off consultation just before the decision.
- As to the impact of the participation:
  - A non-binding advice is exceptionally chosen by those who are not in the organs (only one person chooses this option out of 30 in the first scenario and 10% in the second one), and although a small group chooses this option among those who are members of the organs today, this is still 22% of those respondents in the first scenario and 27% in the second one.
  - Taking the advice into account during decision-making is more often chosen by the non-members (respectively for scenario 1 and 2 43% and 33% of this group) than the members (respectively 17% and 20%).
  - The need to justify the decision is the preferred option for both groups, but in the scenario on consulting the citizen, this is based on a small majority for the non-members (16 out 30 persons), and a stronger majority for the members (66%).

Figure 9 – Model chosen to CONSULT the CITIZEN with regard to setting global priorities for resource use allocation in health care

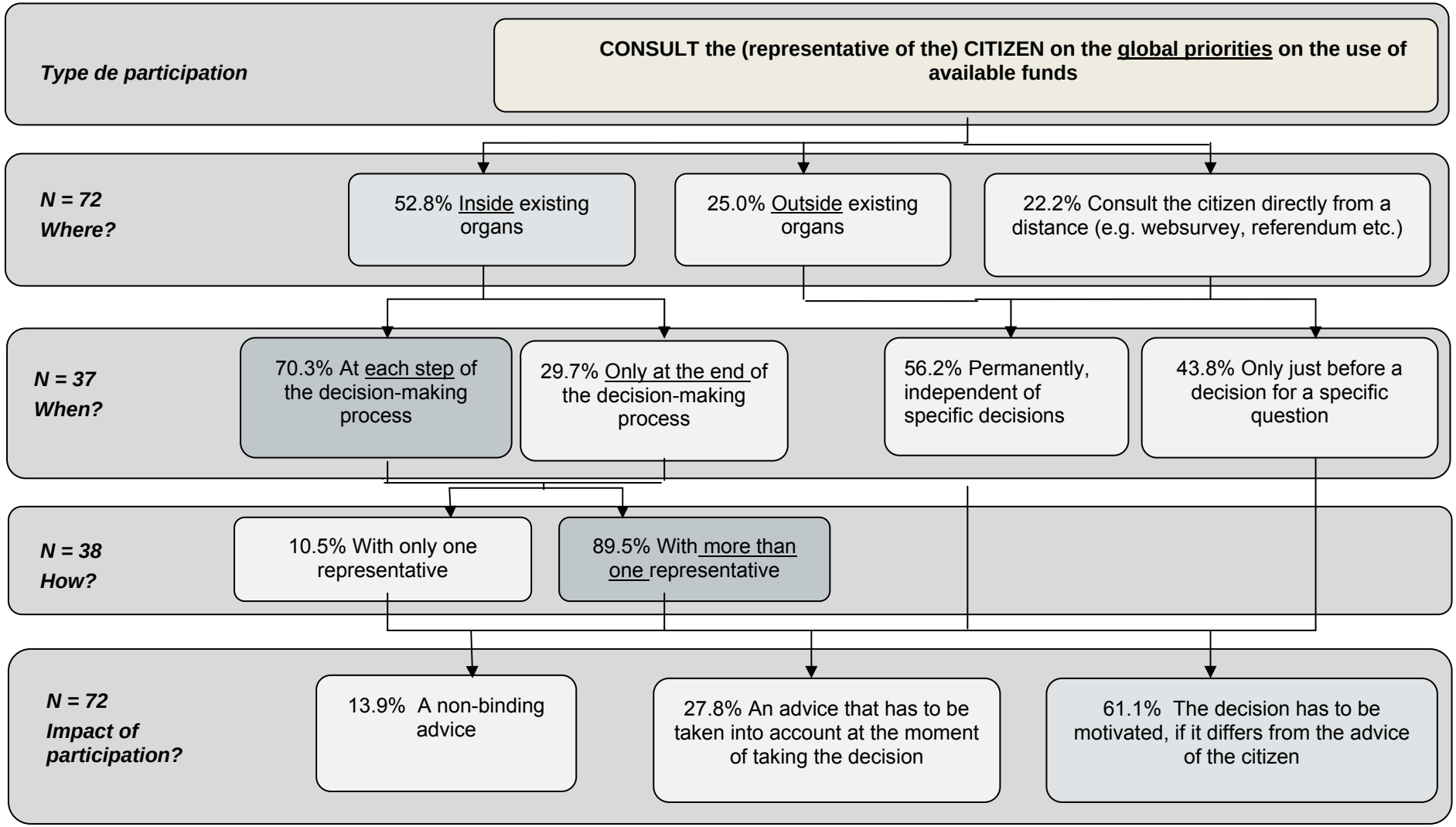
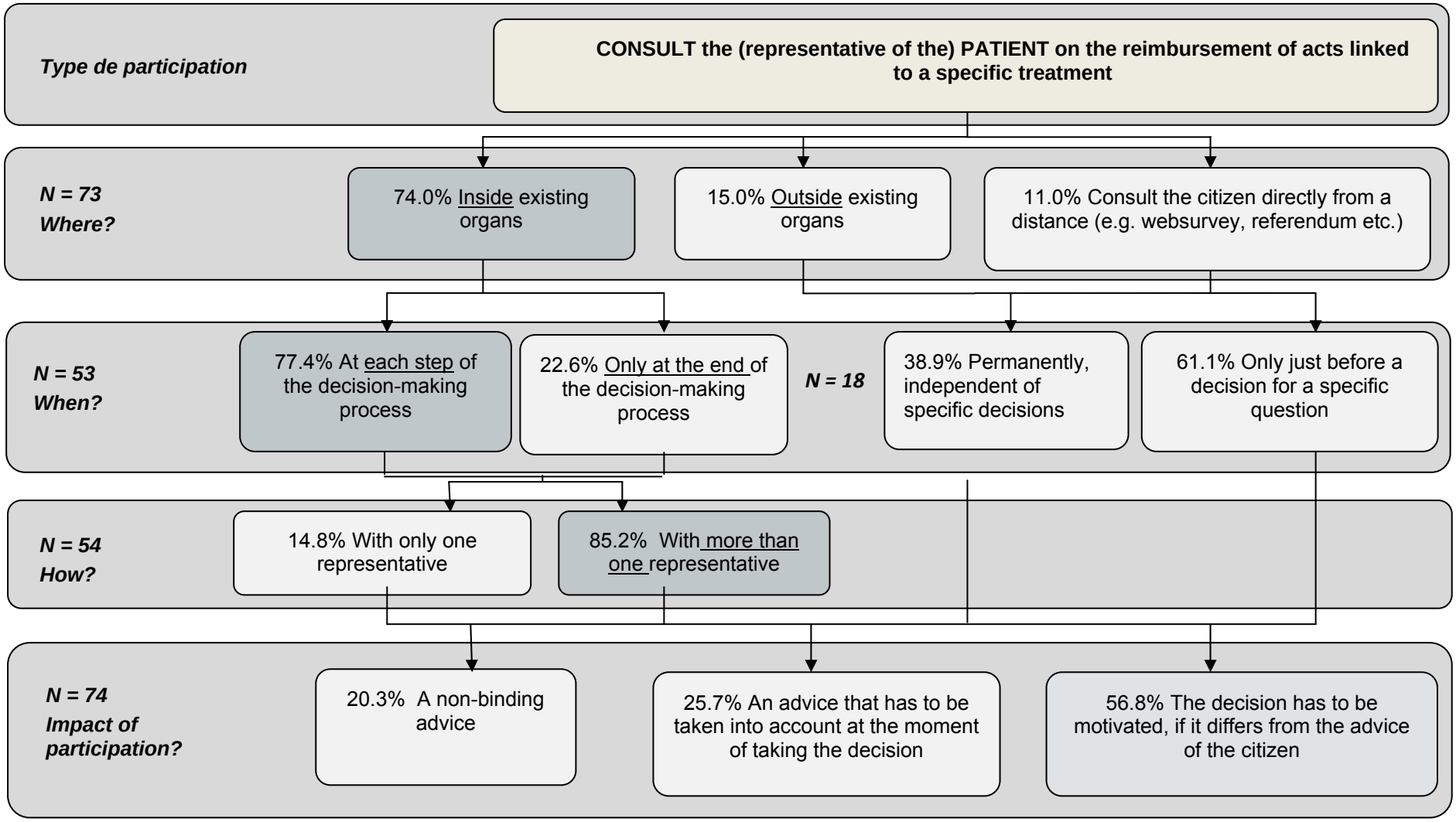


Figure 10 – Model chosen to CONSULT the PATIENT with regard to decisions related to reimbursement of acts linked to a specific treatment



4.3.10. The representation of citizens and patients

From the comments during the first round of the Delphi survey, different points of view emerged regarding who actually represents the public and patients today. This could affect the interpretation and answers to the questions.

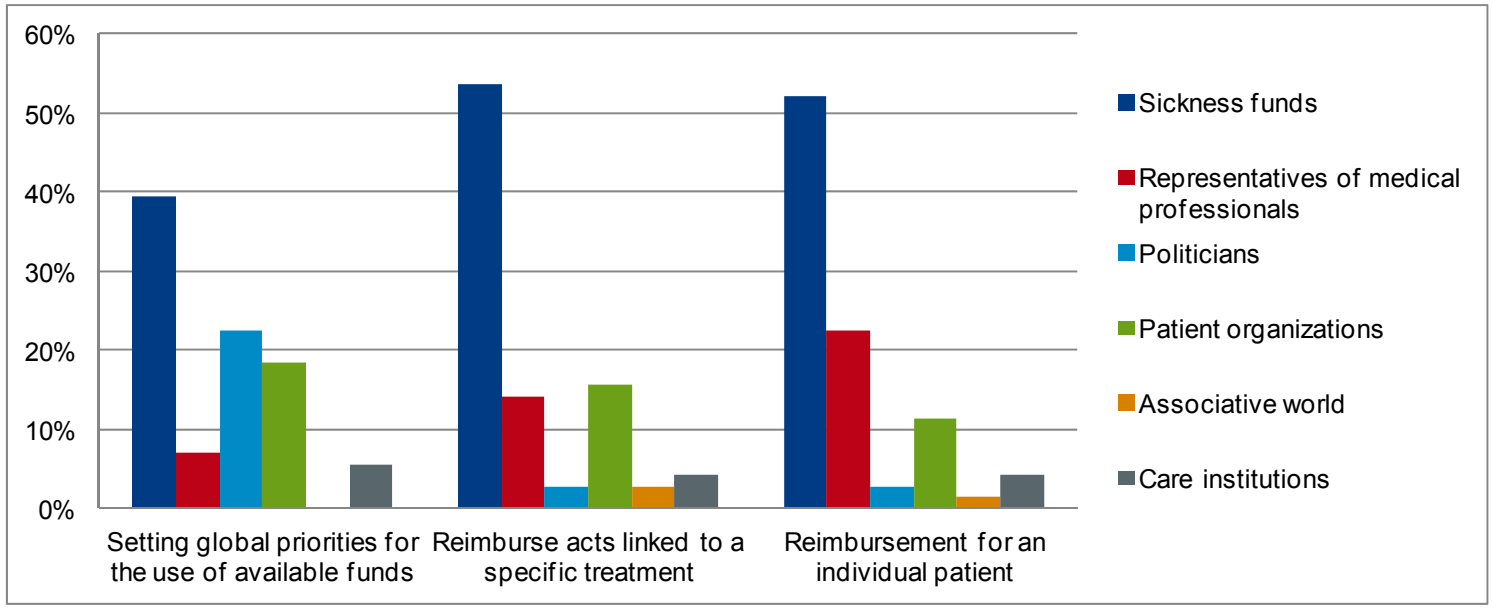
This is particularly the case for the sickness funds: a small number of respondents who work for these organisations explicitly stated that their response should be interpreted in the understanding that sickness funds can be considered to represent the patients.

To better understand the opinions of participants as to who represents the public and patients, a double question was included in the second round: one on who represents the public and patients today, and one on who would ideally represent the public and patients in the future.

4.3.10.1.Who represents the public and patients today?

The sickness funds were chosen as the current representatives of the public and patients by the majority of the respondents for all types of decisions related to the reimbursement (Figure 10). The figure below gives the percentages of the choice as *most important* representative today. Sickness funds have been chosen most often for all three decisions considered and even by more than 50 % of participants for two types of decisions. Representatives of medical professionals are much less considered as current representatives of citizens and patients for decisions relating to the reimbursement of products for an individual patient (slightly more than 20% of the respondents chose this option). For decisions related to the priorities for the allocation of health care funds, the sickness funds were still chosen by almost 40% of the respondents, but here the contrast with two other stakeholders was less striking. The politicians and patient organisations were also considered to represent citizens and patients by about 20% of the respondents. In the case of specific reimbursement decisions, patient organisations seem to play more often this role just before the representative of medical professions. Finally, these last ones are perceived as representing more often citizens and patients for individual decision than patient organisation.

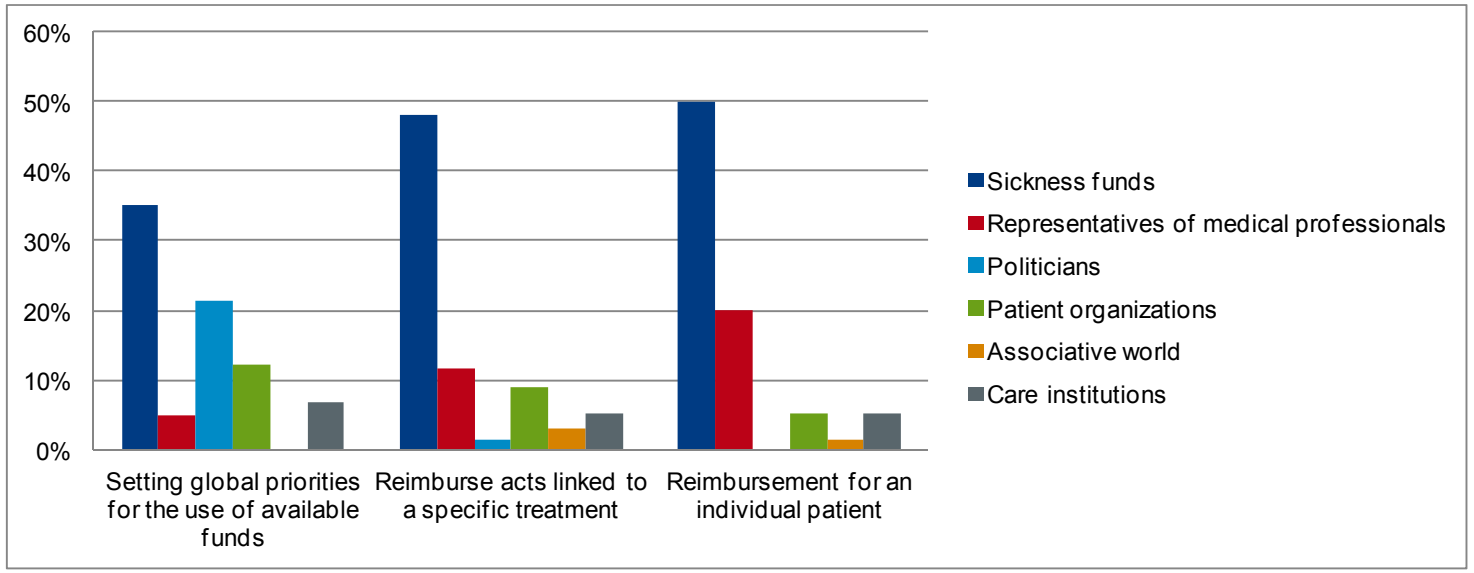
Figure 11 – Current best representative of the public and patients today by type of decision (N=71)



Based on Table 16 in appendix

It can be argued that these results are due to participants referring to their own stakeholder group as being the best representative of the citizens and patients. However, excluding self-referrals from the responses shows exactly the same pattern (Figure 12), although percentages are in general lower for all representatives. It should be noted that it was not possible to remove the self-referrals from the results for the representatives of medical professionals and for the care institutions because several respondents in this category belonged to both.

Figure 12 – Current best representative of the public and patients today by type of decision, excluding self-referrals



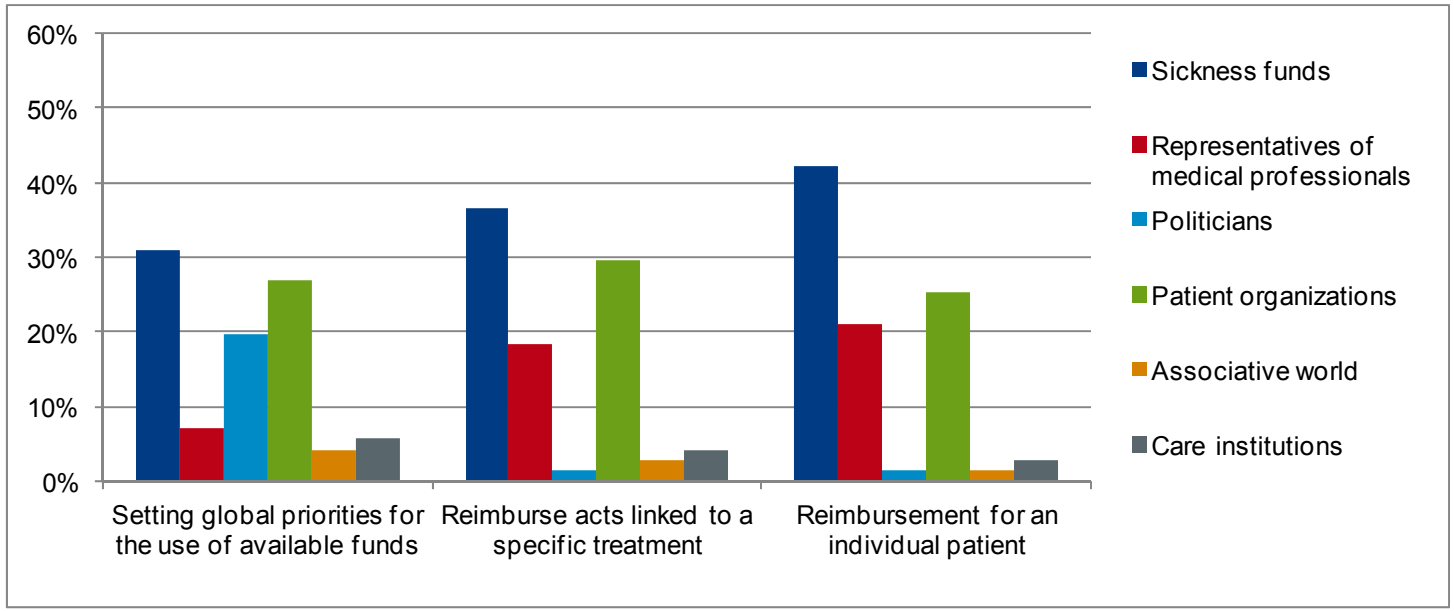
The results per type of stakeholder show that:

- **respondents from patient organisations** (N=15) position the sickness funds before the patient organisations in their top 3 of representatives of the public and patients for all types of decisions, even for reimbursement decisions for an individual patient. Care institutions are also chosen for the latter decision type.They choose much less often the politicians for global priority setting: only 4 out of 15 (against 59% on average for all respondents), which places politicians well after the representatives of medical professions and care institutions.
- **respondents who are civil servants** (N=13) are quite in line with the global sample, except that they give slightly more weight to the politicians, and less to the representatives of the medical professions for global priority setting. In addition, they never choose patient organisations for reimbursement decisions for specific treatments, and only one respondent selected patient organisations as representative of the public and patients for decisions about reimbursement for an individual patient.
- **representatives of the medical professions and care institutions** (N=20): for global priority setting, they select more often the patient organisations, select less often the politicians; select only slightly more the medical professional organisations (and not the care organisations). They present no difference with the full sample for their position on the representativeness of the different stakeholders in decisions related to specific treatment or to an individual patient; they select less often the sickness funds for individual patient decisions: 9/20 do not select them in the top 3.
- **politicians** is a very small sample (N=6), but 5 out of 6 choose politicians in the top 3 for decisions on setting global priorities and this is consistent for the other decisions (e.g. 3/6 chose them in the top 3 for specific treatments).
- **respondents from sickness funds** chose for their own group for all kinds of decisions but are quite in line with the general classification of the other stakeholders groups.

4.3.10.2.Who should ideally represent the public and patients?

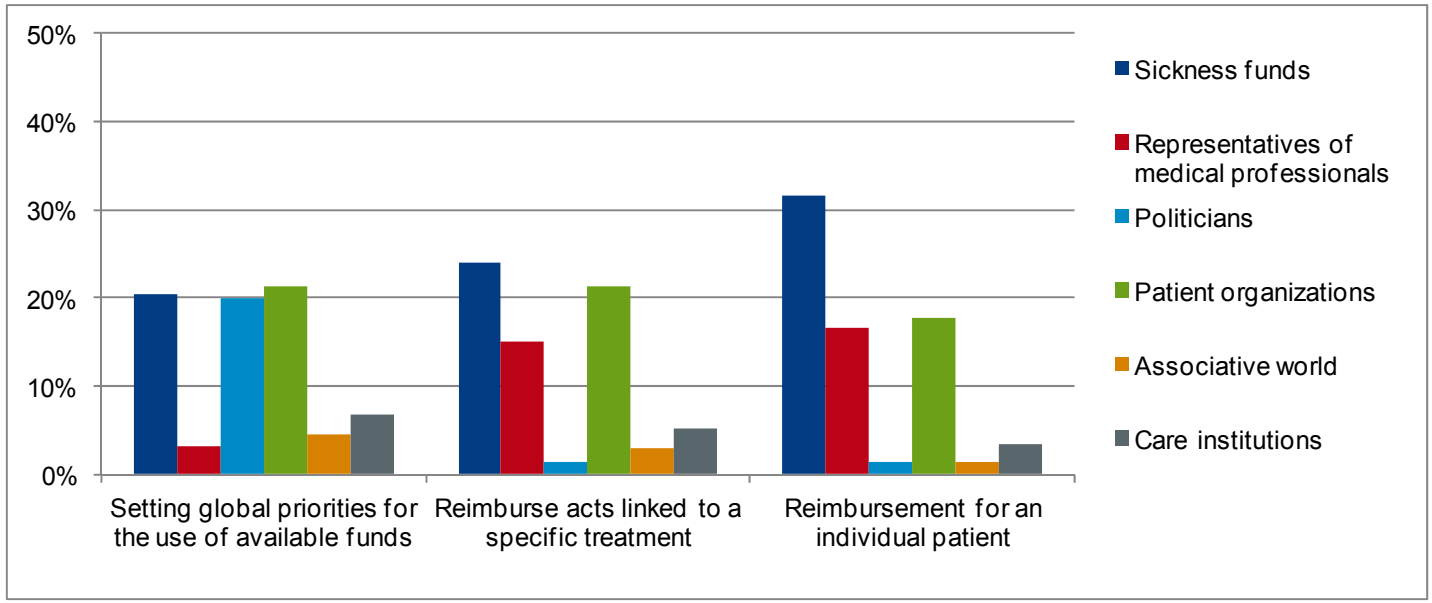
Sickness funds are again mentioned most often as the 'ideal' representative for all three types of decisions if self-referrals are not excluded (Figure 12). After exclusion of self-referrals, sickness funds become slightly less frequently ranked as best representative for decisions relating to setting global priorities for health care resource allocation than patient organisations (Figure 14). The difference is too small, however, to conclude that patients are considered to be better representatives than sickness funds. It can be concluded, however, that for this type of decisions, the respondents consider that patient organisations and sickness funds should be considered at the same level, which contrasts with the current situation.

Figure 13 – Best representative of the public and patients by type of decision (N=71)



Based on Table 16 in appendix 4

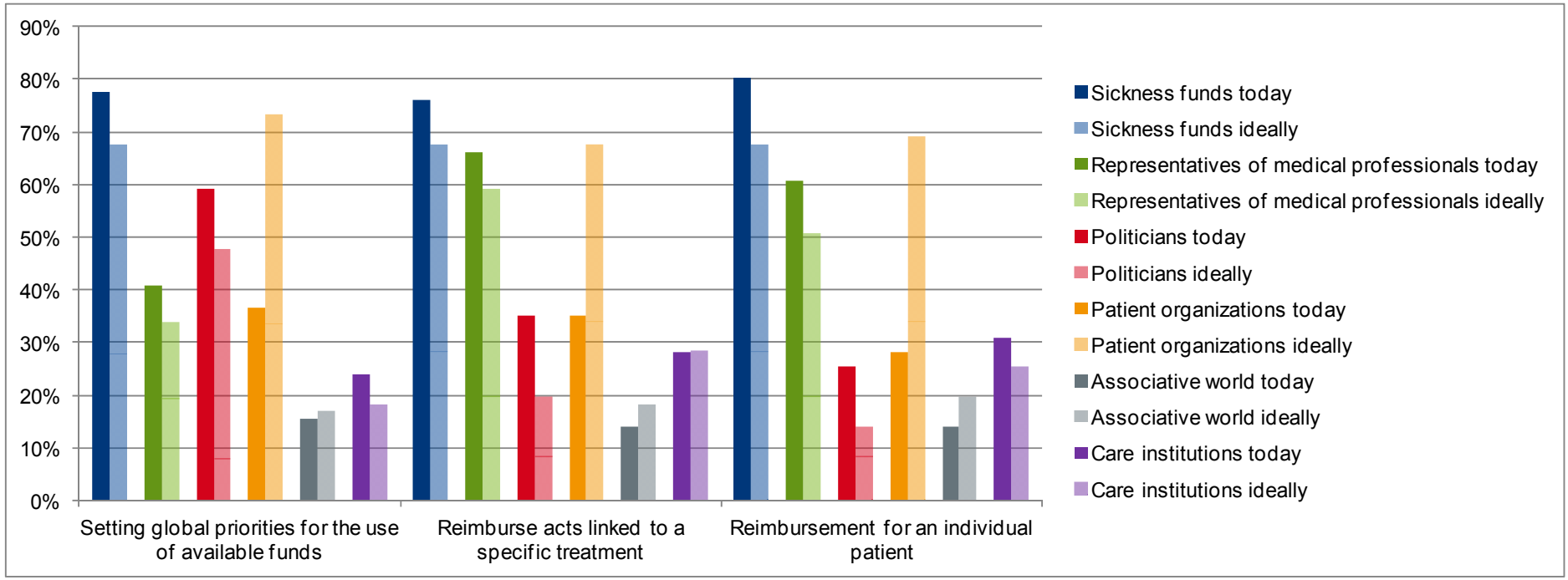
Figure 14 – Best representative of the public and patients by type of decision, excluding self-referrals



4.3.10.3. Desired evolution of representation

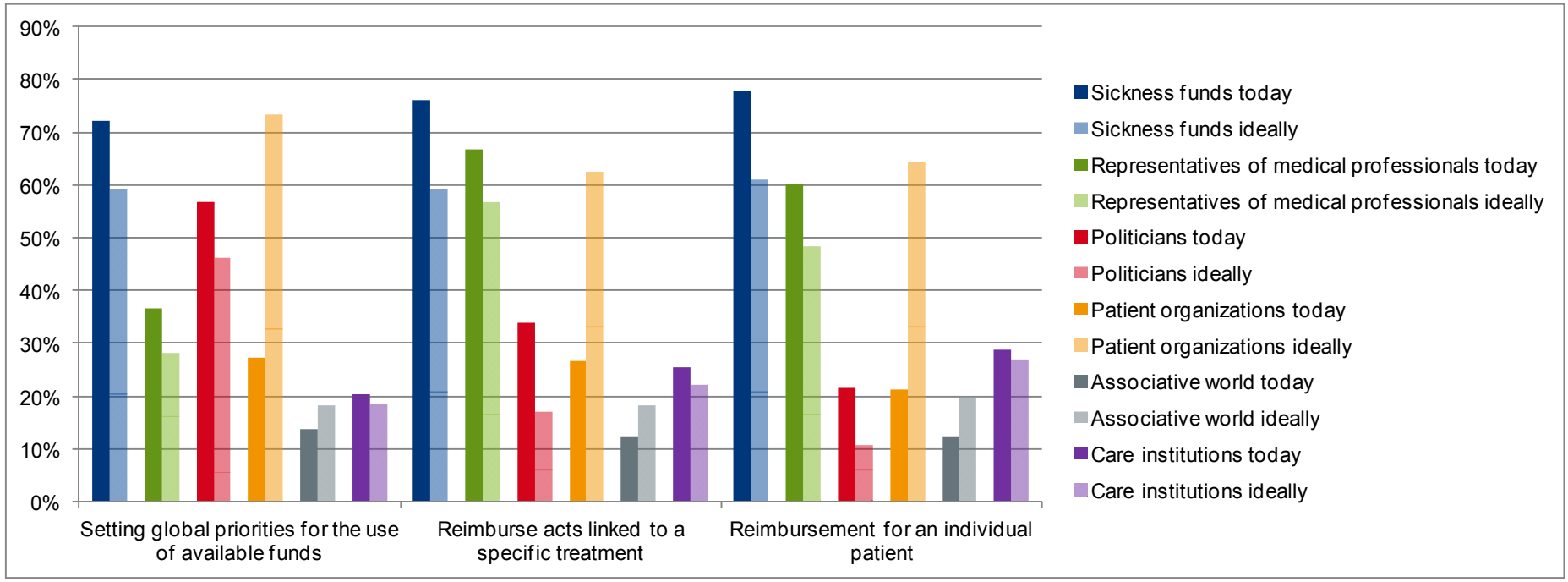
Figure 14 and Figure 16 provides a comparison between the perceived current situation and the expressed ideal situation, based on the choice among the *top 3* representatives (and not only the first choice as in the previous two figures). The data show how the Delphi panel considers that representativeness of the public and patients has to evolve in the 3 concrete types of decisions.

Figure 15 – Who represents the public and patients today compared to the ideal situation in Belgium by type of decision (top 3) - % of valid answers (N=71)



Based on Table 17 in appendix 4

Figure 16 – Who represents the public and patients today compared to the ideal situation in Belgium by type of decision (top 3), excluding self-referrals



For the total sample in the three types of decisions, there is a clear general preference towards more weight for patient organisations, although the sickness funds remain an important public and patients representative. The patient organisations reach a level comparable to the level of the sickness funds for all types of decisions. The only other stakeholder category that is gaining on all three types of decisions (even if small gains) is the associative world.

The results also show that there is not one specific stakeholder category whose role is reduced to increase the role for patient organisations.

Of the 71 valid responses, 13 give identical answers for the situation today and the ideal situation. These respondents are coming from patient organisations (4 out of the 15 respondents from this stakeholder group), sickness funds (5/17) and the service-supply side (medical professions and care institutions – 4/20).

The other 58 responses see movements in various directions. These responses were analyzed to understand the main "movements" from today to an ideal situation. Some of these movements are minor (low), e.g. the same stakeholders, but the hierarchy from 1 to 3 is changing. Other movements are strong, e.g. the stakeholder who is in an ideal situation the best to represent the patient, has no role today.

The main movements are:

- From sickness funds to patient organisations: a total of 19 respondents (out of 58 who see a change between today and the ideal). Of these 19 respondents, 8 see a strong movement and 11 a rather low level of change. For 4 out of 19, the movement from sickness funds to patient organisations is the only move they see; for the other 15 persons, this is one of the moves they consider.
- Other moves away from the sickness funds are less often considered. Still, a total of 13 respondents see moves away from sickness funds towards various other stakeholders. Most often mentioned are medical professional representatives (4) and the associative world (3)
- 8 respondents see a move away from the patient organisations. This is mainly towards sickness funds and politicians. None of these respondents are linked to a sickness fund or civil servants. They are mainly medical professionals and politicians.

Details on the movements towards the "ideal" representative by stakeholder category are presented in appendix 4, under table 17.

5. DISCUSSION AND CONCLUSIONS

5.1. Relevance of public and patient involvement

In a democratic social health insurance system, like in Belgium, policy decisions in health care should in principle reflect societal values. Involvement of citizens and patients in the decision-making process is one way to try to achieve this aim. Also in Belgium, societal and economic evolutions, such as an increasing demand for health care and higher patient expectations in combination with financial constraints, have raised the interest in public and patient involvement. In addition, legitimating health care policy decisions becomes increasingly important.

Today, in Belgium, a deliberation-driven model of decision making incorporates several stakeholders (i.e. scientists, sickness funds, pharmaceutical industry's representatives, medical and health care institutions representatives) in an deliberative appraisal committee. It is assumed that by this means health care policy decisions reflect public values, without involving patients or citizens directly and explicitly. Despite initiatives to consult patients and citizens for general policy questions, e.g. by sickness funds, or general representation of citizens by state representatives, it is unclear to what extent patients and citizens are involved in decisions on particular issues, e.g. the reimbursement of a new product or service.

Little research exists, though, on which model for public and patient involvement is most effective in which circumstances. The current study describes different models for public and patient involvement in health care decision-making and assesses their acceptability in Belgium.

Despite a growing body of literature on public and patient involvement, the concept of public and patient involvement remains poorly defined. This goes together with conceptual vagueness throughout the literature concerning who are the 'public' and 'patients' in public and patient involvement and which roles they can take in the decision-making process. Which actors are involved is considered here to be an analytic choice. The 'public' may refer to citizens, consumers, tax- and social contributions-payers, lay people, service users, and patients. Every citizen is a patient, a service user, a consumer of health care services and a tax- and social contributions-payer. Being a 'citizen' or a 'patient' is not a status, but rather a role one adopts in a specific context. It depends on the content of the questions a person has to answer and the perspective he/she (has to) adopt(s) when answering the questions whether he acts as a citizen or a patient. The citizen cannot be 'separated' from the patient because every citizen can/will become or has been a patient at a certain moment in time.

5.2. Relevance of this study

Before citizen and patient involvement in health care decision-making processes can even be considered, its importance and acceptability amongst the stakeholders should be checked. The success of the implementation of public and patient involvement initiatives depends on the acceptance of both the principle and the modalities. This study aimed to contribute to these uncertainties for Belgium.

The acceptability of different models or modalities of public and patient involvement was evaluated by means of a 2-round Delphi survey among Belgian stakeholders currently involved or not (yet) involved in the decision-making processes. To our knowledge, this is the first survey performed on this topic in stakeholders currently involved (or not) in health care decision making processes.

A wide range of stakeholders was invited to participate in the survey, including politicians, high-level civil servants and policy makers at national, regional and community level, all members of decision-making organs at the RIZIV – INAMI, consumer associations and patient associations. All types of stakeholders were represented amongst the 107 participants in the first round of the Delphi panel. Eventually, 80 stakeholders participated in both Delphi rounds. Participants were asked to express their personal opinion and not the opinion of their organisation.

The Delphi survey provided clues about the acceptability of public and patient involvement for Belgian stakeholders. However, the paucity of evidence in the literature on the most appropriate participation model in a given context implied that we had to evaluate multiple possible scenarios and that –even if the principle of public and patient involvement is accepted– it will remain uncertain whether a concrete involvement initiative could be defined for Belgium and whether this initiative will be successful.

It was beyond the scope of this study to work out the concrete modalities and implementation of a public and patient involvement model. Further efforts are needed to achieve this goal.

5.3. Main findings

Little research exists in literature on which model of public and patient involvement is most effective in which circumstances. Involvement has several dimensions, related to the intensity, place, timing, technique and consequences of the involvement.

Intensity refers to the extent to which citizens and patients have control over the decision-making process. Involvement may imply, in increasing order of intensity, informing, consulting, debating, co-decision making, and letting the public or patients decide.

According to the literature the best way of engaging the public in priority setting is to use multiple participation methods, to engage multiple publics, and to use methods at different levels of intensity, in order to get a more differentiated understanding of the public's and patients' values. A potential threat to the success of public and patient involvement is the imbalance of powers between involved stakeholders.

Empirical literature shows that citizens or patients may not desire to be involved or share the responsibility in decision making, or may vary in their willingness to be involved in health care decisions.

From the Delphi study the following main findings can be highlighted. First, there was a high level of consensus regarding the importance of involving the public and patients in health care decision-making. The small minority of respondents who did not consider public and patient involvement as important (8%) is spread over different categories of stakeholders, rather than concentrated in one specific group.

Second, the most important potential benefits identified by the respondents were the possibility to take the needs and priorities as experienced by citizens and patients into account, the introduction of the quality of life dimension in addition to the therapeutic and diagnostic dimensions and the responsibilization through a better awareness about the challenges and costs. Next to these perceived benefits, the reasons for public and patient involvement mentioned in the Delphi survey are multiple, with no clearly dominant one, and cover the different rationales indicated in the literature. Therefore, we can conclude that all the theoretical perspectives prevail as rationale for public and patient involvement in Belgium.

Third, most risks identified by the Delphi panel relate to the potential imbalance of power, such as insufficient means (human, financial) to participate effectively, the risk for patients to be instrumentalized, and the lobbying or power games of other stakeholders. In addition, the difficulty of an adequate representation to express a collective opinion is mentioned. Next to these, there is also a perceived risk of subjectivity. Nevertheless, there is consensus that the benefits of public and patient involvement outweigh the risks. All specific risks mentioned by the participants are to be considered as symptoms of a more general risk. The more general risk is that the involvement asked from citizens and patients in a collective endeavour may be jeopardized by the highly individualized world we currently live in. To avoid or solve these risks of citizen and patient involvement we have to find a way to move from the individual concern or individual responsibility to the collective concern or the collective responsibility. Indeed, not only individual but also collective responsibility is needed to relate the citizen to the solidarity system, to make him conscious of the role he/she can play to build up the system. Theoretically, we could imagine to put the citizens and patients behind a 'veil of ignorance' as proposed by Rawls and Dworkin.[72-76] Concretely, even if this can seem to be a paradox, we can obtain the same result by giving enough information to make the people conscious that frailty is consubstantial to the human living. Information about the socioeconomic gradient in health and health care consumption, information about the lack of a systematic link between lifestyle en the health status (e.g. cancer is not always the result of non sanitary lifestyles) can motivate people to take part at a solidarity system. In other words, if people think that they deserve their income and deserve their 'good health', they probably do not want to contribute to a solidarity system. They will probably consider that everybody have to be individually responsible. A better informed individual becomes capable of reflecting behind 'a veil of ignorance' because he/she also becomes 'skeptical' about his/her own merit and becomes ready to finance and to construct a solidarity system.

Fourth, the Delphi panel reached consensus on all success factors. These include training of citizens and patients as well as other stakeholders to contribute effectively to the decisions. However, there is a risk that professionalisation creates a distance between participants and those they claim to represent. There was also agreement on the need for transparency, recognition and funding of patient organisations, the development of a participation culture, and support of all stakeholders. This corresponds with the conclusion of Van Bovenkamp et al. (2010) that the development of an opportunity structure for public and patient involvement is a necessary but not a sufficient condition to make public and patient participation work in practice.[64] Although the opportunity structure does not deny access, it can still inhibit participation for example because organisations are unable to attend.

Fifth, the majority of the respondents perceived the sickness funds as currently representing the public and patients in the health care decision-making processes. This applies to all types of decisions: resource allocation priorities, product reimbursement and reimbursement for individual patients. When asked about their preferences regarding who would ideally represent citizens and patients, respondents still chose sickness funds as the best representative, although the relative importance of patient organisations increased compared to their current position. This finding suggests that the current role of the sickness funds as public and patients representatives is not questioned by the stakeholders, but that nevertheless there is room for a more prominent future role of patient organisations and the associative world. However, the results have to be interpreted with caution, because we compared an existing situation, with a potential situation. The effects of the involvement of sickness funds are well known. Everybody has an idea about its benefits and limitations. However, the consequences of involving patient organisations are still uncertain. The experience is lacking, but is expected to be positive.

Finally, based on a comprehensive literature review and the existing national health care reimbursement decision-making structures in Belgium, we developed scenarios for public and patient involvement. A scenario is determined by the subject of the decision, who represents the citizens and patients for each type of decision, the intensity of public and patient involvement, and the participation method**.** The developed scenarios were presented to the Delphi panel. A consensus appeared from the first round that citizens should be involved for strategic decisions (setting budgetary priority) and patients for more operational decisions (e.g. product reimbursement decision linked to a specific disease).

The preferred minimum level of intensity of public and patient involvement and the role of the citizens and patients involved depends, however, on the type of decision. In our Delphi panel, consensus has been reached in the following aspects:

- for setting global budgetary priorities in health care, the public and patients, representing the citizens should at least be informed and consulted;
- for decisions about the reimbursement of particular products, the representative of the patients should at least be informed and consulted;
- for decisions related to the reimbursement of health care products for a particular patient, there was no consensus on public and patient involvement.

There is also consensus about the possibility to debate with citizens and patients, but this is not considered as a minimal requirement. No consensus was reached regarding the need for co-decision-making, i.e. involving citizens and patients in every aspect of the decision-making process. Decision-making by citizens or patients alone is rejected as an option for all types of decisions.

The preferred scenario for public and patient involvement, according to our Delphi panel, is to consult citizens or patients, within the existing decision-making organs at each step of the decision-making process rather than only at the end. More than one representative of citizens or patients is preferred to only one representative. Decisions ought to be motivated whenever they differ from the advice provided by the representatives. While this is considered as a feature of consultation in our models, having to motivate a decision if deviant from the advice of citizens and patients could actually be considered as a form of participation in the debate, which is a higher intensity of participation. Compared to the alternatives from which respondents could also chose, this was actually the most demanding scenario for all types of decisions and the two levels of

involvement for which a scenario had to be chosen. This finding indicates that participants in the Delphi panel are serious about this subject.

A scenario definition is insufficient, though, for the implementation of citizen and patient involvement. It needs to be complemented with methods of involvement. This is the subject of ongoing research as the KBF.

These results suggest that the interpretation of respondents of "consultation" resembles what the IAP2 describes as "participation in the debate". The respondents also show a high level of conformism: novel techniques are not considered, quite certainly because they are not known or experience is lacking.

5.4. Remaining issues

Our study has a number of limitations. We used the intensity ladder of involvement proposed by the IAP2 as point of departure, without questioning the different degrees of intensity. However, a number of authors have criticized this hierarchical approach to public and patient involvement. For example, Litva et al. (2002) show that the preferred intensity of involvement of members of the public lies between consultation and "involvement", where involvement is defined as a kind of partnership with responsibility for decision making shared between professionals and the public.[2] In the terminology used in this report, this corresponds with "participation in the debate". Consultation refers to "*an opportunity for individuals to express their views, but offer[ing] no guarantee that individual views will be taken into account*" (Charles and DeMaio, 1993[1], cited by Litva et al., 2002). Litva et al. (2002) conclude that there is a considerable gap between these degrees of participation. The informants in their study wanted their involvement to be located within this gap.[2] Our scenarios in the Delphi survey were limited to informing and consulting patients and citizens, because these two levels of intensity came out as the preferred levels in the first Delphi round. Although we did ask about the acceptability of participation in the debate as a maximum level of intensity of involvement in round 2, it was not included in the scenarios. Therefore, we cannot draw conclusions about the ideal scenario for citizen and patient involvement if participation of debate would be chosen as the level of intensity.

In our Delphi survey, we did not take into account the option of "accountable consultation", i.e. the contribution to decisions by expressing views with the guarantee that this contribution will be heard, without responsibility for the decision, but with a look on the rationale for the decision ultimately made. A judgement on the preferable impact of the involvement has, however, been included in the scenarios presented to the panel in the second Delphi round. Respondents had the choice between 1) a non-binding advice, 2) an advice that has to be taken in consideration at the moment of taking the decision, 3) an advice that has to be taken into consideration in the decision and has to be motivated if the decision deviates from the advice. Both in case of global priority setting and in case of decisions linked to specific treatments, the majority of respondents preferred the last option (61 and 57% respectively). This finding corresponds with the findings of Litva et al. (2002).[2] In this regard note that it is unclear from what intensity on participation actually starts. One could argue that informing and consulting is not (yet) really participating. To what extent does the consensus about the fact that decisions different from the advice of citizens or patients should be motivated imply a certain participation in the debate instead of consultation only. In line with the research findings of Litva et al. (see above) a six level typology could be suggested.

Second, we included several kinds of stakeholders in health care policy, as well as patient organisations, although these are much less involved in the current health care policy. We did not include individual citizens or patients in our Delphi panel. Hence their perspective is only partially integrated in this study, through the voice of patient organisations. Other authors (e.g. Litva et al., 2002; Lomas, 1997) found that in some situations some citizens or patients do not desire to be involved, nor share in the responsibility. Lomas (1997) concluded that "*the public do not feel comfortable in making choices, that they reject the task as requiring expertise that they do not possess, and that elicitation of underlying values and principles is the only area in which they see themselves as appropriately involved*".[77] In other words, the public and patients may feel quite happy with others making these difficult choices in health care for them. This relates especially to specific reimbursement decisions and decisions regarding individual patients, but apparently less for setting

global priorities in health care. Litva et al. (2002)[2] found variations in the willingness of members of the public to be involved in health care decisions. There was a strong desire to be involved both at the system and programme levels, but much less willingness to be involved at the patient level. This corresponds with the results of our Delphi panel, where citizens and patients are seen as having no role in decisions for individual patients.

Third, the Delphi survey approach and our implementation of it has some specific methodological weaknesses. For instance, the delays inherent to the method are short. This is particularly a challenge between the first and second round. This leaves very little time to analyse and describe the results to include them in the second round. Moreover, the short period had an influence on the response rate; particularly for the second round as some respondents were on holiday. However, the high level of consensus reached in a short period of time, proves the appropriateness of the method in this particular case.

Fourth, the current study should be considered as a first step in a longer process of assessing the potential benefits of patient and citizen involvement. We have tested the 'acceptability' of citizen and patient involvement and explored modalities for a possible implementation. The next steps would be to test the actual implementation and to evaluate such a citizen and patient involvement process. Public and patient involvement is but one way to introduce public values and preferences into the decision-making process. Complementary approaches could be, for instance, to measure in a scientific way and preferably recurrently the public's values and preferences for health care priority setting, and use this information in actual decision-making processes as a kind of external data source, which could also be used to increase consistency and transparency in the decision-making process.

Finally, we focused on health care decision-making and excluded studies that examined involvement in service development, shared decision-making of individual treatment, clinical decisions, therapeutic and service delivery decisions, and clinical guidelines. We also excluded studies about public and patient involvement in health research or non-health fields such as environmental sciences and urban planning. This way we might have missed issues which could also be relevant in a health care decision-making context, but were not included in the Delphi study.

5.5. Stakeholders' comments

The results of the current study were presented to a group of stakeholders during a face-to-face meeting. All stakeholders initially invited to participate in the Delphi survey were invited to the meeting. Thirty-nine people from all stakeholder groups were present.

The discussion during the stakeholders meeting was concentrated around 4 major themes: (1) the possible redundancy of a separate endeavour to involve public and patient given the existing deliberative structures in Belgium, (2) the potential risks of public and patient involvement in decision-making at the strategic level, (3) the basic values and principles that should guide the public and patient participation, (4) the independence of patients associations and the absence of opposition between patients and citizens and between patients associations and sickness funds and finally the requirements for success (5)

Ad (1): The potential redundancy of a separate approach for citizen and patient involvement refers to the currently already active representation of several stakeholders in the current decision-making structures. Especially in the context of defining priorities in health care, reference was made to the parliament representing the public, the sickness funds representing the patients. In this respect, we would like to clarify that the type of involvement discussed in this report is supposed to be complementary to the role of the members of the parliament and sickness funds. More specifically, in order to be able to adequately represent the public and patients, member of the parliament and sickness funds should dispose of the necessary knowledge with respect to the public values and patients' preferences. For this purpose, they should consult the public and patients and could even let them participate in the debate by putting forward the issues at stake setting up a discussion on these issues.

An additional point was made that patient organisations are also capable of representing the consumer of health care, which is in line with our definition of a "patient representative". As argued in 3.2, the terms refer to a role representatives play in the decision making process. Patients can take two different roles: either that of the expert by experience or that of the health care consumer. This does not mean, however, that patients can *only* be represented by patient organisations. Consumer organisations, taking the perspective of the consumer of health care, could also fulfil this role.

Ad (2): It has been evoked during the meeting that patient involvement at the operational level might be acceptable for getting input from people with expert knowledge through experience, but that involvement at the strategic level carries multiple risks. One of the risks identified is the potentially strong influence of media on the preferences of the public. Our response to this comment is twofold. First, there is no evidence that this influence would be higher for patients or the public than for the other stakeholders actually involved in the decision-making process. Of course, patients or citizens participating in the process should be well-informed about the issues at stake and the decisions to be made. Besides this, there is no reason to assume that the current experts in the decision-making organs, expressing the preferences of their stakeholder group, are less amenable to influences by the media. Secondly, citizens and patients involved in strategic decisions are supposed to bring in knowledge about the values and preferences of the general public. It is clear that they would need the necessary input to play this role effectively. This input could come, for instance, from a survey about values and prioritization criteria, as will be collected in the next KCE report on this topic. A second risk identified would be the possible 'instrumentalisation' of the citizens to justify 'difficult and sensible' decisions. For instance, in a context of budgetary limitation, the citizens could accept to 'limit' specific health care for the older people to increase the budget possibilities in order to reimburse health care for young and active (productive) people. The existing empirical evidence rather shows that people are capable of 'empathy' and can make real 'collective' choices and not only 'personal' choices. Besides this, the organisers of citizens/patients consultations have to be sure that the group of representatives is really significantly representative of the whole population.

Ad (3): In our report, we distinguish three possible principles for public and patient involvement in the decision making process: the consequentialist, the democratic and the capacitating principle. During the discussion at the stakeholder meeting, the issue was raised that on the strategic -and to a lesser extent the operational- level, a guiding principle for citizens may be a larger degree of autonomy for patients. If citizens/patients are well informed it becomes possible to give them the progressive 'capability' to make personal and collective choices and to assume these choices, personally but also collectively. This comment fits perfectly into the capacitating principle, where the emphasis lies on giving patients and citizens the opportunity to take their responsibility for their own choices. Of course, we have to consider the real capability to be autonomous and free before to take any decision concerning the responsibility of the patient.

Ad (4): Because the 'status' of patient or citizen is linked to the context, to the content of the consultation, to the type of question, we cannot be afraid for and opposition between 'patient' and 'citizen'. Everybody is a 'citizen' and a 'patient', successively and even simultaneously. The sickness funds and patients associations have complementary roles to play to give a 'voice' to people considered as 'insured' and to the people considered as 'patients suffering from a given pathology'. Associations of patients, but also of citizens, have to be independent from lobbying and one way to become / to stay independent can be provided by a sufficient 'neutral' financing.

Ad (5): The major requirement for success of a public and patient involvement initiative highlighted during the meeting was the provision of means and information to the representatives. Moreover, some participants emphasized the importance of explaining the specific challenges to the patients and citizens that would participate. Some considered this to be a difficult requirement, potentially jeopardizing the feasibility of public and patient involvement in decision-making processes.

5.6. A final reflection

The study reveals a high level of consensus on the importance of citizen and patient involvement. Taking into account the fact that two out of three respondents are today part of the decision-making bodies with regard to reimbursement, this shows a high level of openness to change.

Even though the study reveals this consensus on the importance of public and patient participation and on a positive benefit/risk balance, there seemed to be no openness to a complete overhaul or major revision of the present system. Changes are seen as having to take place within the current structures. Based on the results of the Delphi survey, strong resistance can be expected from a small group of people; maximally about 10% of the stakeholders. In the Delphi survey, these opponents came from different stakeholder groups participating in the Delphi panel.

There is little knowledge and experience with the subject. This may temper the positive attitude as may the fear for change, for something unknown among persons involved in decision making today. Most respondents had no idea of how the value of participation could be created in practice, with which techniques and with which type of representation. Respondents who did have experience with participation, evaluated this experience as predominantly positive.

Sickness funds were considered to be the stakeholder group that is today de facto representing (most) the citizens and patients in the decision-making process. In an ideal world, experts did see a much more prominent role for patient organisations than they have today, bringing them to a level comparable to that of sickness funds. This change is coming from all stakeholder groups, including the respondents from sickness funds. In this ideal situation, the position of the sickness funds as representing the citizens and patient was globally maintained, even though it is sometimes criticised in terms of conflicts of interest and in actually taking up this role. At the same time, also a risk of instrumentalisation of patient organisations is perceived, as well as similar concerns regarding conflicts of interest. By extension, the conflict of interest concern could apply to every stakeholder involved in the decision-making process. This shows that experts consider that the roles of both stakeholders is complementary rather than in competition.

According to the majority of the stakeholders participating in the Delphi panel public and patients could be involved at different levels, with different levels of intensity

Participants were able to define a scenario for informing and consulting citizens and patients in specific decisions on health care reimbursement. At the same time some risks inherent to public and patient involvement have been identified in the literature as well as by the Delphi panel. Critics have expressed concerns about public and patient involvement as purely “window dressing”, the lack of representativeness of the public and patients, the professionalization of the public and patients, and a lack of evaluation of the effectiveness of public and patient involvement.[78] These (perceived) risks need to be taken into account in the design of public and patient involvement initiatives in Belgium.

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