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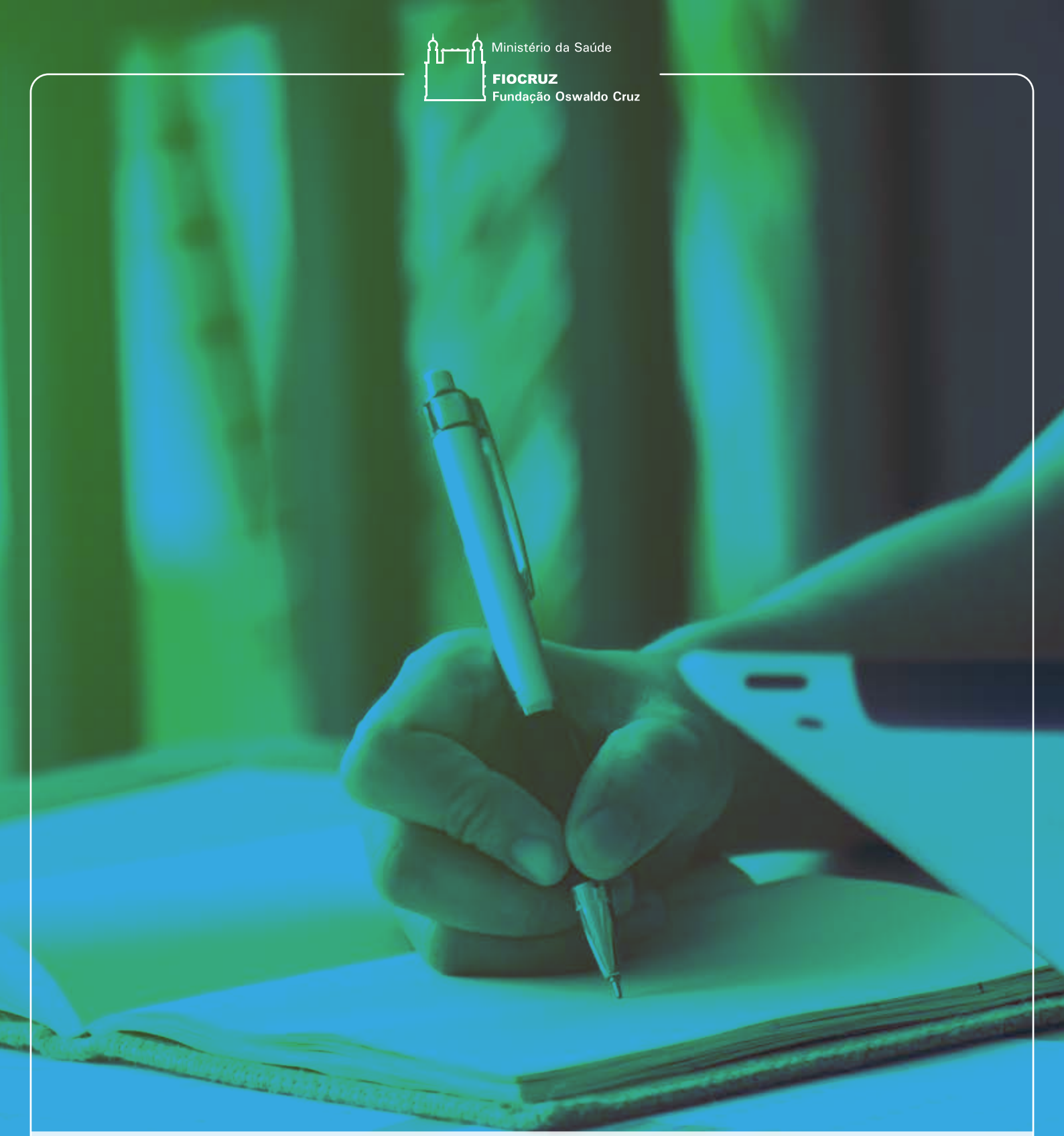

APRIMORAMENTO DA GESTÃO DE TECNOLOGIAS NO SUS

PLATAFORMA DE TRADUÇÃO, INTERCÂMBIO E APROPRIAÇÃO SOCIAL DO CONHECIMENTO

Participação Social na Avaliação de Tecnologias em Saúde para Sistemas de Saúde: Achados de Uma Síntese de Evidências Qualitativas

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2020 Ministério da Saúde.

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Sumário

1 Introdução

Este relatório foi orientado pela demanda do Departamento de Gestão e Incorporação de Tecnologias e Inovação em Saúde (DGITIS), secretaria executiva da Comissão Nacional de Incorporação de Tecnologias ao SUS (CONITEC) da Secretaria de Ciência, Tecnologia e Insumos Estratégicos do Ministério da Saúde do Brasil (MS). Para o DGITIS, faz-se necessário aprimorar e expandir os mecanismos pelos quais a sociedade (pacientes, médicos, cientistas e outros) tem participado do processo de avaliação de novas tecnologias de saúde. Para tanto, pareceu-nos apropriado começar por uma revisão das iniciativas que têm sido implementadas em outros países, sobretudo aqueles em que o engajamento social tem sido mais aprofundado e diversificado (como Austrália, Canadá, Reino Unido, Alemanha entre outros). Portanto, a ideia de realizar uma síntese de evidências qualitativas[1]. Assim, apresentamos aqui os achados dessa síntese de evidências qualitativas sobre modelos e métodos de participação social na avaliação de tecnologias em saúde para sistemas de saúde.

Os objetivos deste relatório são:

a. explicar a metodologia da síntese de evidências qualitativas, incluindo a seleção de artigos e o processamento dos achados (seção 2).
b. apresentar os diferentes tipos de modelos de participação social, numa classificação que seja útil para uma agência como o DGITS a partir de uma síntese interpretativa dos achados da literatura (seção 3).
c. oferecer uma síntese meta-agregativa dos achados da literatura, de modo a explicitar as barreiras e facilitadores encontrados em países estrangeiros (seção 4).
d. com base nesses achados, oferecer algumas diretivas iniciais para o estabelecimento de iniciativas de participação mais sofisticadas e efetivas do que aqueles que são atualmente utilizadas no Brasil (seção 5).

2 Síntese de Evidências Qualitativas: metodologia

Desenvolvemos uma revisão sistemática para sintetizar o conjunto de evidências global sobre o tema 'participação social' intitulada "Identificação de modelos e métodos para 'participação / engajamento / consulta / empoderamento de pacientes / social / público(a)' em processos de avaliação de tecnologias em saúde (ATS) e tomada de decisão sobre cobertura em sistemas de saúde: uma revisão sistemática", cujo protocolo foi registrado na plataforma Prospero (CRD42017068714) para fins de transparência e acompanhamento global de nosso trabalho, em 5 de junho de 2017. Seguimos a diretriz PRISMA-P[2] – *Preferred Reporting Items for Systematic review and Meta-Analysis Protocols* – uma lista de verificação com a recomendação de itens a serem abordados em protocolos de revisões sistemáticas).

Consideramos adequado desenvolver uma revisão sistemática da literatura para abordar esta questão pois, o levantamento prévio da literatura apontou a publicação de diversos tipos de estudos relevantes – incluindo revisões sistemáticas, revisões rápidas, revisões de escopo, relatórios de ATS, sínteses para políticas informadas por evidências (*policy briefs*) e artigos primários de pesquisa qualitativa, quantitativa e de métodos misto originais publicados em periódicos indexados como estudos de caso – recentes e com potencial de cobertura de grande parte das iniciativas de participação social em processos de avaliação de tecnologias em saúde e tomada de decisão sobre cobertura. Deste modo, descrevemos as etapas da revisão sistemática desenvolvida que embasou ambas sínteses interpretativa e meta-agregativa, uma vez que "uma revisão de uma pergunta claramente formulada que utiliza métodos sistemáticos e explícitos para identificar, selecionar e avaliar criticamente estudos relevantes, e coletar e analisar dados dos estudos incluídos na revisão" [3].

2.1 Perguntas da Revisão Sistemática

As perguntas que embasaram esta revisão foram desenvolvidas para o contexto de sistemas de saúde e verificaram:

a. Quais são os modelos e métodos de 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' em processos de ATS e tomada de decisão sobre cobertura?
b. Quais são os facilitadores e barreiras chave identificados na literatura internacional sobre 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' em processos de ATS e tomada de decisão sobre cobertura?

2.2 Estratégia de Busca na Literatura

A pesquisa na literatura foi realizada utilizando os seguintes bancos de dados eletrônicos: PubMed, *Cumulative Index to Nursing and Allied Health Literature* (CINAHL), EMBASE, *The Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Methodology Register), Health Technology Assessment Database, Health Systems Evidence*, PDQ-Evidence, Epistemonikos, *Centre for Reviews and Dissemination (CRD – Database of Abstracts of Reviews of Effects/DARE e Health Technology Assessment/HTA*), PsycINFO, LILACS, Scopus, Google Scholar, e *Web of Science* (*science and social science citation index*). Incluímos literatura cinzenta e listas de referência de estudos que contemplados pelos critérios de seleção.

A estratégia de busca combinou termos (indexadores) de pesquisa relacionados a 'participação social' (*Social / Patient / Public Participation / Engagement / Consultation / Empowerment / Citizen Science*) e processos de tomada de decisão em avaliação de tecnologia em saúde e cobertura (*Militancy / Lobby / Advocacy / Health Technology Assessment / Decision Making / Life Sciences / Medicine / Biomedical Sciences*). Os termos foram adaptados para as estratégias utilizadas nas bases de dados eletrônicas pesquisadas e estão compilados no Anexo 1 (Anexo 1 – Estratégias de Busca Bases de Dados Eletrônicas).

As buscas foram realizadas até 17 de novembro de 2017 para a inclusão de novos artigos (de forma específica, isso aconteceu para a síntese interpretativa – seção 3). Esta estratégia de busca foi repetida em 14 de novembro de 2019 para atualização.

Não houve nenhuma restrição de país, idioma ou data da publicação.

Os termos (indexadores) foram pesquisados em título e resumo, exceto onde indicado de outra forma no Anexo 1. Os estudos resultantes da busca realizada nas bases acima mencionadas foram inseridos no programa de gerenciamento de referências Mendeley para seleção de estudos, e as duplicatas foram removidas.

2.3 Critérios de Inclusão

Os estudos foram selecionados de acordo com os critérios abaixo:

2.3.1 Tipos de Estudos

Incluímos revisões sistemáticas, revisões rápidas, revisões de escopo, relatórios de ATS, *policy briefs* e artigos primários originais publicados em periódicos indexados como estudos de caso que discutem, comentam e analisam criticamente modelos, métodos e estudos de caso de 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' em processos de avaliação de tecnologias em saúde e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde. Revisões e artigos originais que discutem 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' a respeito de doenças específicas e/ou processos de tomada de decisão sobre cobertura, tais como abordagens para o autogerenciamento de estados de saúde individuais e/ou coletivos NÃO foram considerados IRRELEVANTES e NÃO foram DESCARTADOS. Incorporamos evidências qualitativas

junto de revisões quantitativas, quando consideramos relevante e oportuno, conforme segue sinalizado nas seções 3, 4 e 5 de apresentação de resultados.

2.3.2 Contexto (Critérios de Exclusão)

NÃO consideramos elegíveis publicações sobre processos de tomada de decisão compartilhada sobre intervenções (bio)médicas específicas dentro de contextos de relação profissionais de saúde e pacientes. Também NÃO incluímos publicações cujo resumo não estava disponível (online) com um título que não incluísse algum termo (indexador) relevante para as estratégias de busca elaboradas para cada base de dados eletrônica. Também NÃO incluímos estudos de caso exemplificando apenas 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' em estudos clínicos não especificamente desenvolvidos e/ou direcionados para informar processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde. Por fim, também NÃO incluímos resumos de congressos e estudos que não estavam disponíveis em formato completo para análise.

Estabelecemos um critério de exclusão para a etapa de leitura de publicações completas: NÃO incluímos publicações que não descrevessem métodos e/ou modelos que foram (in)eficazes em informar processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde (isto é, nacional, estadual, municipal, institucional/local e internacional/regional).

2.3.3 Tipos de Participantes / Populações

Os participantes foram considerados quanto aos tipos de grupos populacionais (atores sociais) com potencial interesse sobre o assunto 'participação social em processos de ATS e tomada de decisão sobre cobertura – isto é:

a. a sociedade, composta por cidadãos e/ou consumidores atuando como pacientes, seus familiares, cuidadores e representantes legais, além de grupos de pacientes e de advocacy;
b. profissionais em saúde, incluindo profissionais de saúde em todos os níveis de sistemas de saúde, pesquisadores, formuladores de políticas e tomadores de decisão (gestores) envolvidos em processos de desenvolvimento, avaliação, implementação, monitoramento e reavaliação de tecnologias em saúde e formulação de políticas em tais contextos.

2.3.4 Tipos de Intervenções

Consideramos como relevantes e elegíveis todos os modelos e métodos de 'participação/ engajamento / consulta / empoderamento social / público / de pacientes' em processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde (isto é, nacional, estadual, municipal, institucional / local e internacional / regional).

2.3.5 Comparador

Não aplicamos restrições quanto ao comparador

2.3.6 Desfechos Primários

Procuramos identificar modelos e métodos de 'participação / engajamento / consulta / empoderamento social/ público / de pacientes' em processos de ATS e tomada de decisão sobre cobertura para alcançar um entendimento consistente sobre sua implementação (procedural) para processos de tomada de decisão e formulação em contextos de saúde.

2.3.7 Desfechos Secundários

Também procuramos identificar publicações detalhando questões-chave sobre barreiras e facilitadores identificados na literatura internacional sobre 'participação / engajamento / consulta / empoderamento

social / público / de pacientes' em processos de ATS e tomada de decisão sobre cobertura para em sistemas de saúde para ajudar a aprimorar e qualificar a governa de tecnologias em saúde e arranjos de prestação de serviços, assim como suas estratégias de implementação.

2.4 Triagem e Seleção de Estudos

Os títulos e resumos dos registros recuperados foram selecionados por dois revisores de modo independente (M Sharmila A Sousa – MSAS – e Mabel F Figueiró – MFF). Em seguida, o texto completo dos estudos potencialmente elegíveis foi avaliado de forma independente para finalizar a seleção. Desacordos em relação à elegibilidade dos estudos foram resolvidos por discussão e consenso e, quando necessário, por um terceiro revisor. O processo de triagem e os resultados foram relatados de acordo com a lista de verificação PRISMA (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses* – Principais Itens para Relatar em Revisões sistemáticas e Metanálises)[4].

2.5 Extração dos dados (Seleção e Codificação)

Dois revisores (MSAS e MFF) selecionaram títulos e resumos dos registros recuperados de forma sistemática e independente. Os resultados de interesse (título, autores, ano, populações, tipo de estudo [revisões sistemáticas, revisões rápidas, revisões de escopo, relatórios de ATS, *policy briefs* e artigos primários originais publicados em periódicos indexados como estudos de caso], modelos e métodos, processos de avaliação de tecnologias em saúde e tomada de decisão sobre cobertura, níveis de sistemas de saúde, resultados de implementação, barreiras e facilitadores) também foram extraídos de forma independente por duas duplas de revisores, de acordo com o tipo de síntese de evidências - interpretativa (MSAS e Edison C Bicudo Jr - ECBJ) e meta-agregativa (MFF e Vicky N Pileggi – VNP) de acordo com o protocolo pré-definido e resumidos em uma tabela de síntese de achados pelos quatro revisores (MSAS, MFF, ECBJ e VNP) padronizada para coleta e síntese de dados em planilhas de Excel, conforme elaboradas por MSAS. As planilhas foram comparadas para conferência dos dados extraídos e sintetizados por MSAS (síntese interpretativa) e por MSAS e MFF (síntese meta-agregativa).

Os achados da síntese interpretativa (seção 3) permitiram a construção de uma tipologia que nos permitiu categorizar os achados da síntese meta-agregativa (seção 4), de acordo com o referencial teórico estabelecido segundo a revisão sistemática da literatura. Os achados de ambas as sínteses interpretativa e meta-agregativa nos permitiu a construção de um quadro de apoio à tomada de decisão (seção 5) para agências de ATS e cobertura para quaisquer níveis de sistemas de saúde (isto é, nacional, estadual, municipal, institucional/local e internacional/regional).

2.6 Avaliação da Qualidade Metodológica

A qualidade metodológica das revisões sistemáticas foi conduzida por uma dupla de revisores (MSAS e MFF) de forma independente pela aplicação dos critérios baseados no AMSTAR 2 - *A MeaSurement Tool to Assess systematic Reviews 2*[5]. Os desacordos foram resolvidos por discussão e consenso. As avaliações completas de cada revisão sistemática incluída estão compiladas no Anexo 2 (Anexo 2 – Tabela Resumo Avaliação AMSTAR 2 das Revisões Sistemáticas Incluídas nesta Síntese de Evidências Qualitativas).

A confiança dos achados desta síntese de evidências qualitativas foi avaliada segundo os critérios da abordagem GRADE-CERQual[6,7]. Para tal, foi necessário avaliar a qualidade metodológica de todos os tipos de estudos recuperados (isto é, revisões sistemáticas, revisões rápidas, revisões de escopo, relatórios de ATS, sínteses para políticas informadas por evidências (*policy briefs*) e artigos primários de pesquisa qualitativa, quantitativa e de métodos misto originais publicados em periódicos indexados como estudos de caso) por uma dupla de revisores (ECBJ e VNP) de forma independente através do uso dos critérios listados no CASP (*Critical Appraisal Skills Programme, 2018 – Checklist for Qualitative*

Research). Os desacordos foram resolvidos por discussão e consenso, e/ou por um terceiro revisor (MSAS). As avaliações completas de cada publicação incluída estão compiladas em pasta de arquivos que será compartilhada via dropbox em conjunto com todos os achados por país, planilhas de inclusão, extração, síntese e avaliações CASP para cada publicação incluída nesta síntese de evidências qualitativas.

A construção dos achados, seguindo os critérios da abordagem GRADE-CERQual, foi realizada por uma dupla de revisores experientes em pesquisas qualitativas e revisões sistemáticas (MSAS e ECBJ) e a avaliação do grau de confiança em cada um dos achados desta síntese de evidências qualitativas foi conduzida por outra dupla de revisores (MFF e VNP) de forma conjunta. Os desacordos foram resolvidos por discussão e consenso, e/ou por um terceiro revisor (MSAS). As avaliações completas de cada publicação incluída estão compiladas nas tabelas de achados que seguem nas seções 3, 4 e 5.

2.7 Análise dos Dados

As descrições das experiências de cada país e/ou organizações / agências promotoras de ATS (por país) com modelos e métodos de participação social em ATS e demais resultados sobre barreiras e facilitadores de implementação de tais modelos e métodos (por tipo de modelo e método) estão discutidos de forma narrativa nas seções 3, 4 e 5, com o apoio de tabelas de achados, com as respectivas avaliações sobre o grau de confiança segundo os critérios da abordagem GRADE-CERQual, registros recuperados que contribuíram para o respectivo achado e comentários a respeito de suas limitações para os fins desta síntese de evidências qualitativas para apoiar a tomada de decisão do DGITS.

2.8 Análise de Subgrupos

Diferentes categorias de análise e apresentação dos achados (síntese meta-agregativa – seção 4) sobre 'participação/ engajamento / consulta / empoderamento social/ público / de pacientes' em diferentes níveis de sistemas de saúde nos diversos países foram elaboradas segundo:

a. achados gerais sobre participação social em processos de ATS e tomada de decisão sobre cobertura em diferentes níveis de sistemas de saúde (Tabela 1 – Tabela de Achados Gerais sobre Modelos de Participação Social; pg.12);
b. as etapas do processo de ATS das organizações / agências promotoras de ATS (Tabela 2 – Tabela de Achados sobre Participação Social em Organizações / Agências promotoras de ATS por País; pg.17)
c. os modelos de participação social (isto é, informação, consulta e participação – *empoderamento e #ciência cidadã – Tabela 3 – Tabela de Achados Específicos sobre Modelos de Participação Social por País; pg.35);
d. experiências de países (e/ou de organizações / agências promotoras de ATS) com modelos de participação social em processos de ATS - e etapas anteriores (formulação de políticas, desenvolvimento) e posteriores (implementação e monitoramento) das (novas) tecnologias em saúde (Tabela 4 – Tabela de Achados sobre Experiências sobre Modelos de Participação Social em Processos de ATS e Etapas Anteriores (Formulação de Políticas, Desenvolvimento) e Posteriores (Implementação e Monitoramento) de (Novas) Tecnologias em Saúde; pg.49).

3 Participação Social: síntese interpretativa

Neste relatório adotamos a expressão 'participação social', que é utilizada no Decreto n° 8243 de 23/05/2014 da Política Nacional de Participação Social[8]. Sempre que falarmos em participação social, fazemos referência às várias formas por meio das quais os cidadãos (sejam eles pacientes, médicos, enfermeiros, cientistas, jornalistas, cuidadores, indústria ou outros) interferem no processo de ATS,

expressando suas demandas, preocupações, reclamações, conselhos, e assim por diante. Sendo assim, a participação social permite que, na ATS, a organização / agência promotora possa levar em consideração questões que poderiam ser ignoradas caso critérios técnicos e econômicos, apenas, fossem considerados. Também ressaltamos que, neste relatório, quando descrevermos especificamente as metodologias dos diferentes tipos e graus de participação social, utilizaremos a expressão 'engajamento social'[9,10] como sinônimo de 'participação social', conforme acima descrito, para evitar redundância terminológica.

3.1 Tipos e Graus de Participação Social

Sistemas de saúde de alguns países têm cada vez mais encorajado e aperfeiçoado a participação ativa da sociedade na tomada de decisões durante todas as etapas da gestão da incorporação – desde o desenvolvimento passando pela avaliação, até o monitoramento da implementação – de (novas) tecnologias e serviços em saúde. A maneira através da qual a sociedade se engaja com tais processos varia consideravelmente entre organizações / agências promotoras de ATS e países[11]. Isso não tem conduzido, entretanto, a um consenso quanto ao vocabulário que se deve empregar. Na literatura especializada, diferentes autores têm utilizado diferentes palavras e expressões para fazer referência aos mesmos modelos de participação[12]. No âmbito deste relatório, não consideramos oportuno revisar toda a gama de expressões e concepções adotadas pelos vários autores. Todavia, é essencial estabelecermos algumas referências conceituais que balizem nossas exposições.

Por isso, recorremos à primeira e mais utilizada terminologia proposta por Rowe e Frewer[13] que é simples e suficientemente abrangente para nossos propósitos. Esses autores veem o processo de ATS como gerador de um fluxo de informações. Se tal fluxo for verificado apenas no interior das fronteiras da agência de ATS, não se pode falar em participação social. É apenas quando o fluxo de informações cruza tais fronteiras que teremos processos de participação. Porém, isso ainda não é suficiente. É também necessário considerar que a participação social tem diversas modalidades, desde aqueles em que a agência entra numa interação superficial com os cidadãos (consulta) até aqueles em que tal interação é mais completa e profunda (participação). Assim, Rowe e Frewer[13] identificam três tipos de participação social:

a. Informação (ou Divulgação): refere-se a métodos de engajamento nos quais o fluxo unidirecional de informações se dá a partir da organização / agência promotora de ATS para a sociedade e/ou grupos específicos da sociedade – exemplo: a difusão e/ou disseminação por diversos meios (impressos, audiovisuais e/ou digitais) de um guia em linguagem leiga de um relatório de avaliação de uma tecnologia em saúde que forneça informações objetivas e balanceadas para apoiar o entendimento dos atores sociais sobre o problema, alternativas e oportunidades e/ou soluções;
b. Consulta (ou Participação Passiva): refere-se a métodos de engajamento nos quais o fluxo unidirecional de informações se dá a partir da sociedade e/ou grupos específicos da sociedade para a agência de ATS – exemplos: enquete online para pacientes e/ou representações/grupos de pacientes para obter informações deles sobre a escolha de um novo tópico, experiências e potenciais impactos da avaliação de uma tecnologia em saúde, ou percepções sobre um relatório de ATS, sua análise, alternativas e/ou decisões;
c. Participação (ou Participação Ativa, Ativação): refere-se a métodos de engajamento nos quais o fluxo de informações é bidirecional, ou seja, ocorre uma troca de informações entre a agência de ATS e a sociedade e/ou grupos específicos da sociedade, e vice-versa em que, finalmente, lidamos com um modelo em que o grau de interação entre a organização / agência promotora de ATS e a sociedade é máximo pois a sociedade e/ou grupos específicos da sociedade trabalham diretamente com membros de organização / agência promotora de ATS durante todo o processo para garantir que preocupações e aspirações sociais sejam consistentemente compreendidas e consideradas – exemplos: a organização de uma audiência pública reunindo membros da organização / agência promotora de ATS e diversos tipos de cidadãos, com espaço aberto para que todos se manifestem[1] tais como diálogos deliberativos, painéis e júris de cidadãos.

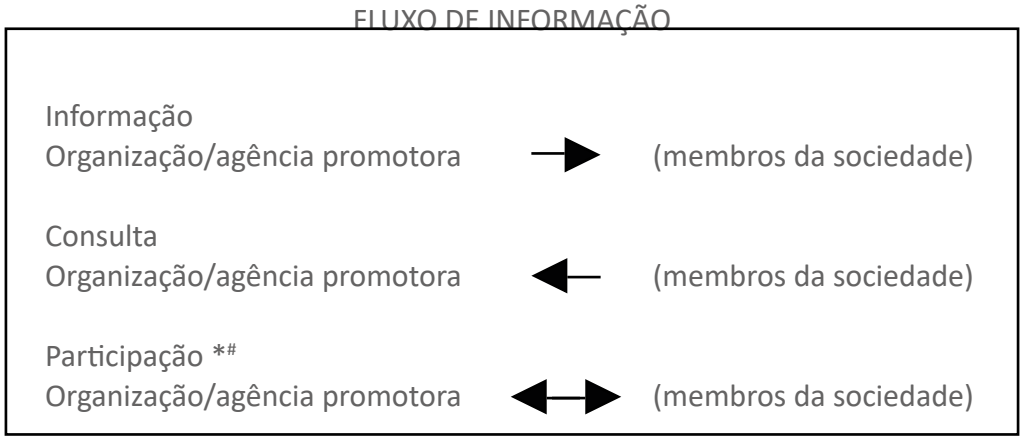
1 Na verdade, Rowe e Frewer utilizam os termos 'comunicação pública', 'consulta pública' e 'participação pública'. Embora estejamos adotando as mesmas ideias, mudamos a terminologia, considerando a tradição institucional brasileira, de modo a tornar nossa exposição teoricamente mais clara.

No modelo de participação (ativa), os processos de diálogo e negociação podem reduzir riscos de interpretações equivocadas e promover uma mudança de opiniões entre ambos agência de ATS e sociedade e/ou grupos específicos da sociedade. Tais métodos de participação ativa devem ser gerenciados pelo nível (local, regional, nacional e/ou direcionado) desejado de participação para o processo de tomada de decisão sobre a tecnologia em saúde avaliada para incorporação e/ou retirada do sistema de saúde[14]. Portanto, Rowe e Frewer nos convidam a pensar a participação social como um grande diálogo entre a agência de ATS e a sociedade. Outros autores também propuseram esse tipo de enfoque dialógico[15]. Sua vantagem é que ele nos permite indagar em que medida os modelos de participação adotados por uma agência de ATS abrem espaço para um amplo diálogo, em vez de constituírem iniciativas de alcance limitado. Neste sentido, são três os motivos que nos levam a adotar o enfoque de Rowe e Frewer. Primeiramente, ele oferece uma útil tipologia de participação social sem atingir um nível de complexidade excessivamente alto. Em segundo lugar, ele nos permite pensar nas iniciativas de participação como um processo comunicativo que pode incluir ou excluir certos grupos (de atores) sociais. Quando o processo de participação é promovido por uma organização / agência estatal, deve-se buscar esquemas de participação social que sejam tão inclusivos e democráticos quanto possível.

O terceiro motivo por que adotamos esse enfoque é de natureza metodológica e operacional. De acordo com os autores, a identificação dos três tipos de engajamento tem por base o 'fluxo de informação'[13]. No primeiro tipo (informação), o fluxo parte da agência com direção à sociedade. No segundo tipo (consulta), o fluxo tem o sentido contrário: da sociedade em direção à agência. Na participação, o fluxo toma os dois sentidos, ou seja, da sociedade em direção à agência e vice-versa, num verdadeiro processo dialógico.

A Figura 1 seguinte ilustra o fluxo de informações nos três tipos de participação social:

Figura 1 – Modelos de Participação Social adaptado de Rowe e Frewer para incluir os conceitos de *empoderamento e #ciência cidadã.



Pensar a participação social do ponto de vista do fluxo de informações é um primeiro passo rumo à operacionalização das iniciativas de engajamento. Pois a organização / agência promotora de ATS, ao mobilizar a sociedade, tem que preparar, difundir/disseminar, receber e processar uma série de informações, sejam elas qualitativas ou quantitativas. No primeiro modelo de engajamento (informação), a organização / agência promotora precisa reunir instruções e dados para apresentá-los a (membros da) sociedade, de modo claro e utilizando os canais adequados à situação. No segundo modelo (consulta), as mensagens partem da sociedade, ficando a organização / agência promotora responsável por recebê-las, armazená-las e interpretá-las. Finalmente, o modelo da participação é mais complexo, já que a organização / agência promotora cria um contexto de diálogo, no qual os envolvidos são emissores e receptores de mensagens. Neste terceiro caso, portanto, instrumentos mais refinados têm que ser mobilizados, para que todos os pontos de vista sejam captados sem distorções.

Estamos então lidando com um "[...] processo de diálogo iterativo e com duas direções, entre representantes da sociedade e a organização / agência promotora da deliberação (pesquisadores, governo ou outras agências)"[15]. O processo democrático pode ficar livre de perturbações se aos cidadãos for a dada a possibilidade de participar de diálogos organizados, com a expectativa de que poderão expressar e ouvir argumentos razoáveis. "Essa reciprocidade de expectativas entre os cidadãos é o que garante a distinção entre um grupo político integrado por uma constituição e uma comunidade segmentada pela divisão entre visões de mundo competitivas"[16]. Assim, é por meio do processo dialógico que se podem minimizar ou dirimir discordâncias e tensões relativas a certa tecnologia social como uma tecnologia de saúde.

No Brasil, até o momento, a participação social em processos de ATS tem consagrado os modelos de informação e consulta[17,18]. Falta, porém, estabelecer modelos mais constantes de verdadeira ativação (ou participação ativa) conforme tem sido fomentado pelas agências de ATS de outros países com sistemas universais de saúde, tais como Canadá e Reino Unido. Neste sentido, este relatório tem como objetivo apresentar ideias, críticas e sugestões que permitam ao DGITS verificar a viabilidade de estabelecimento de tais modelos de ativação. É por isso que é essencial eleger, entre os diversos enfoques existentes, aquele que mais nos possa auxiliar no estabelecimento de parâmetros iniciais que possam balizar iniciativas de fomento à participação social nos processos de ATS no Brasil. Para tais fins, oferecemos um quadro de apoio à tomada de decisão sobre modelos de participação social em processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde (Quadro 1 – seção 5).

Atualizando, portanto, esta tipologia estabelecida por Rowe e Frewer, devido ao aprofundamento das relações estabelecidas entre organizações / agências promotoras de ATS e a sociedade, nossa síntese interpretativa avança na literatura especializada para incorporar e traduzir terminologias sobre os conceitos de *empoderamento – ou seja, a promoção da apropriação da sociedade sobre os processos de ATS e tomada de decisão sobre cobertura em sistemas de saúde[19] – e de #ciência cidadã (e/ou de cidadania) – isto é, iniciativas em que o modelo de produção de conhecimento científico e tecnológico acontece através da colaboração[19] / parceria ou controle social[20] entre (membros da) sociedade e pesquisadores profissionais e/ou organizações / agências promotoras de ATS em cada um dos aspectos da tomada de decisão incluindo a co-produção[21] de tecnologia social[22] – isto é, tecnologia leve / processos[23,24] – como alternativas e a identificação de soluções validadas pela própria sociedade, deste modo, criando uma cultura de promoção do empoderamento da sociedade[10,25]. Aqui o objetivo é evadir abordagens de participação social tokenísticas (ou seja, que envolvem a sociedade sem efetiva participação) e/ou a promoção de habilidades em membros da sociedade para que contribuam competentemente com o estabelecimento de processos de deliberação de qualidade e efetivos. Desta forma, a literatura aponta a necessidade de engajamento social precocemente durante os processos de ATS, incluindo etapas anteriores (tais como formulação de políticas e desenvolvimento) assim como etapas posteriores (tais como implementação e monitoramento de (novas) tecnologias em sistemas de saúde)[14,19,26,27].

Neste sentido, apresentamos os primeiros achados gerais quanto às recomendações da comunidade internacional de ATS sobre como continuamente investir recursos em planejar, desenvolver, implementar, monitorar, avaliar e replanejar abordagens aprofundadas de participação social que incluam estratégias de *empoderamento e #ciência cidadã / colaboração / parcerias – isto é tecnologia social – em processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde. Apresentamos nossos achados seguindo os critérios da abordagem GRADE-CERQual[6,7].

Tabela 1 – Tabela de Achados Gerais sobre Modelos de Participação Social

ACHADO DA REVISÃO	ESTUDOS CONTRIBUINDO PARA O ACHADO	CONFIANÇA NA EVIDÊNCIA	EXPLICAÇÃO DA AVALIAÇÃO DA CONFIANÇA NA EVIDÊNCIA
PARTICIPAÇÃO SOCIAL NO EXTERIOR			
Nos chamados países desenvolvidos, práticas de engajamento público em ATS são comuns.	(28)	Confiança alta	Preocupações menores sobre adequação dos dados (dados são provenientes de apenas uma síntese de políticas).
DEFINIÇÕES E PRÁTICAS			
No plano da teoria, não há na literatura consenso sobre que modelos de participação devem ser utilizados em cada tipo de situação. No plano da prática, os procedimentos de engajamento variam muito de acordo com a organização de ATS.	(29,30,26,19)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Quando a avaliação tem fortes componentes técnicos, o engajamento de técnicos e especialistas é particularmente importante.	(26)	Confiança alta	Preocupações menores sobre adequação dos dados (dados são provenientes de apenas uma revisão sistemática).
As informações colhidas em processos de engajamento requerem uma análise qualitativa.	(26,28)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
As agências de ATS que promovem participação social divulgam os resultados desses processos.	(26,28)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
EFICÁCIA CIENTÍFICA			
Esquemas de participação social favorecem o sucesso biológico da tecnologia.	(31,9,32)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
CIDADANIA			
A participação promove cidadania, permite que os pacientes desempenhem um papel mais ativo na tomada de decisão em saúde e favorece o diálogo social. Por isso, ela gera políticas que tendem a ser mais efetivas e decisões que tendem a ser legitimadas e acatadas mais facilmente.	(31,9,33,32,34,35,36,14,37,38)	Confiança alta	Nenhuma preocupação quanto a todos os componentes componentes CERQual.
Iniciativas de participação podem acabar reforçando exclusões e vieses sociais quando os critérios de inclusão não são cuidadosamente elaborados ou quando se permite que o processo de engajamento seja dominado por alguns participantes.	(39,28,40)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Mesmo com a institucionalização da participação social, pacientes podem permanecer numa posição subordinada, por causa dos poucos conhecimentos e recursos que têm para se juntar a esses processos.	(41)	Confiança moderada	Preocupações moderadas sobre adequação dos dados (dados são provenientes de apenas um estudo (de caso) primário).
PERSPECTIVAS SOCIAIS			
Há na sociedade uma pluralidade de perspectivas, de maneira que pode haver discordâncias entre o que dizem os cientistas e o que espera o público leigo, assim como as visões de pacientes ou de seus representantes podem ser diferentes das visões de outros cidadãos.	(11,42,43,28,15)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.

ACHADO DA REVISÃO	ESTUDOS CONTRIBUINDO PARA O ACHADO	CONFIANÇA NA EVIDÊNCIA	EXPLICAÇÃO DA AVALIAÇÃO DA CONFIANÇA NA EVIDÊNCIA
Os pontos de vista expressos pelo público podem ser bastante gerais e vagos.	(44)	Confiança moderada	Preocupações moderadas sobre adequação dos dados (dados são provenientes de apenas um estudo (de caso) primário).
Iniciativas de participação na internet podem conter vieses por causa de acesso às tecnologias da informação.	(45)	Confiança moderada	Preocupações moderadas sobre adequação dos dados (dados são provenientes de apenas um estudo (de caso) primário).
FORMAS DE PARTICIPAÇÃO SOCIAL			
Uma plena participação social requer a realização de processos de participação constantes, com e engajamento do público em todas as fases da ATS.	(46,29,36)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
A realização de processos de participação requer a reserva de recursos humanos, materiais e econômicos.	(46,39,14)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Quando se pretende promover um engajamento mais profundo e substancial, com a explicitação dos desacordos suscitados por certa tecnologia, é importante realizar iniciativas de engajamento presenciais, deliberativas e abertas, ainda que elas não sejam formas de participação totalmente livres de vieses.	(44,47,15)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
TECNOLOGIAS DE SAÚDE			
Os esquemas de participação devem depender da tecnologia avaliada. Essa noção é frequentemente levada em conta por representantes de agências de ATS, diretores de hospitais e pacientes.	(48-49)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Protocolos de saúde tendem a ser seguidos com mais cuidado quando mecanismos de participação são utilizados em sua avaliação.	(50,14,37)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Quando se trata de tecnologias a serem usadas pelos pacientes, é aconselhável promover a participação de médicos e pacientes. Nesse mesmo sentido, quando a tecnologia será aplicada a um grupo específico, é recomendável que os mecanismos de participação incluam esse grupo. Por exemplo,	(51,52,53,54,49,55, 28,15)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Quando preparadas com o auxílio de participação social, as informações em saúde se tornam mais detalhadas e claras.	(56)	Confiança alta	Preocupações menores sobre adequação dos dados (dados são provenientes de apenas uma revisão sistemática).
ASPECTOS GEOGRÁFICOS DA PARTICIPAÇÃO SOCIAL			
Para que um processo de engajamento seja efetivo, é necessário um prévio conhecimento da população a ser engajada e de seu contexto, um requisito que tem sido observado pelas agências de ATS internacionais.	(39,30,26)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.
Na formulação de iniciativas de participação, tanto o nível local como o nacional têm que ser levados em conta.	(57)	Confiança moderada	Preocupações moderadas sobre adequação dos dados (dados são provenientes de apenas um estudo (de caso) primário).
Os mesmos mecanismos de participação levam a resultados diferentes quando aplicados a contextos diferentes. Por isso, os resultados costumam ser desfavoráveis quando se tentam importar modelos de engajamento.	(43,47)	Confiança alta	Nenhuma preocupação quanto a todos os componentes CERQual.

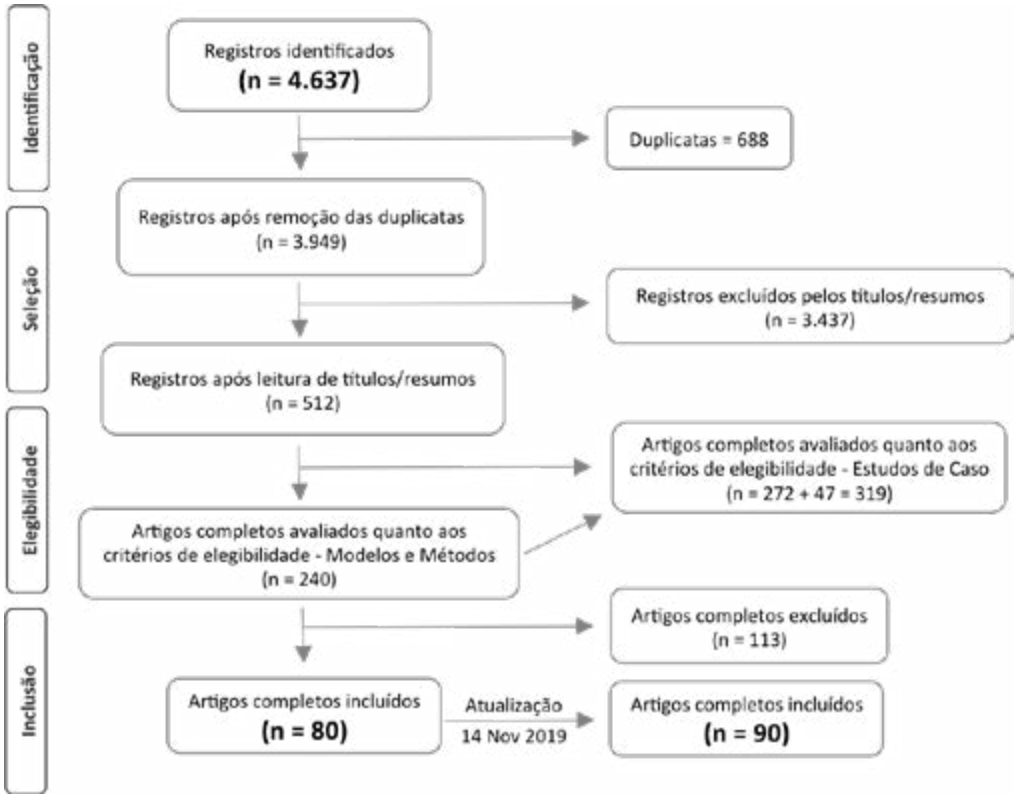
4 Participação Social: síntese meta-agregativa

Descrevemos abaixo os achados desta síntese meta-agregativa, começando pelo relato dos resultados da seleção dos estudos recuperados, e a caracterização dos estudos selecionados. Em seguida, apresentamos os achados específicos quanto às experiências da comunidade internacional de ATS sobre como planejar, desenvolver, implementar, monitorar, avaliar e redesenhar abordagens para cada um dos tipos e graus engajamento social - incluindo estratégias de participação social que compreendam iniciativas de *empoderamento e #ciência cidadã / colaboração / parcerias, isto é, tecnologia social – em processos de ATS e tomada de decisão sobre cobertura em quaisquer níveis de sistemas de saúde. Apresentamos nossos achados seguindo os critérios da abordagem GRADE-CERQual[6-7].

4.1 Seleção dos Estudos

A Figura 2 a seguir descreve o fluxograma do processo de identificação dos estudos relevantes que foram incluídos na revisão. No geral, a pesquisa em bancos de dados recuperou 4.637 artigos, dos quais 240 foram lidos na íntegra. Exclusões após a leitura completa resultaram em 80 estudos que preencheram todos os critérios de inclusão. Este número subiu para 94 após atualização em 14 Nov 2019.

Figura 2 – Fluxograma de Prospecção dos Estudos que Identificaram Modelos e Métodos de Participação Social em Processos de ATS e Tomada de Decisão sobre Cobertura em Sistemas de Saúde



4.2 Características dos Estudos

As características dos artigos completos incluídos estão resumidas a seguir.

Países e tipos de estudos incluídos

— **África:** uma revisão sistemática[39];

— **Alemanha:** duas revisões sistemáticas[49,37], três estudos de caso (artigos originais primários) de pesquisa qualitativa[30,58] e de métodos mistos[54];

— **Austrália:** uma revisão não-sistemática da literatura[59], três revisões sistemáticas[15,49,40], três estudos de caso (artigos originais primários) de pesquisa qualitativa[60,61];

— **ATS internacional (HTAi):** cinco estudos de caso (artigos originais primários) de pesquisa qualitativa[14,51,19,62,63;]
— **Bangladesh:** uma revisão sistemática[39];
— **Benim:** um estudo de caso (artigo original primário) de pesquisa qualitativa[64];
— **Brasil:** uma revisão sistemática[40];
— **Canadá:** onze estudos de caso (artigos originais primários) de pesquisa qualitativa[65,66,38,67,60,53,68,69,70,71,72] e dois de métodos mistos[73,74], quatro revisões sistemáticas[39,49,56,40] e um relatório de ATS[29], uma revisão não-sistemática da literatura e estudo de caso (artigo original primário) de pesquisa qualitativa[42];
— **Chile:** um estudo de caso (artigo original primário) de pesquisa qualitativa[75];
— **China:** uma revisão sistemática[39];
— **Dinamarca:** um estudo de caso (artigo original primário) de pesquisa qualitativa[67,52,75] e uma revisão sistemática[49];
— **Espanha:** um estudo de caso (artigo original primário) de pesquisa qualitativa[76];
— **Estados Unidos da América:** cinco estudos de caso (artigos originais primários) de pesquisa qualitativa[77,45,78,79] e dois de métodos mistos[80,81], cinco revisões sistemáticas[39,49,82,56,40], uma revisão não-sistemática da literatura[59];
— **França:** um estudo de caso (artigo original primário) de pesquisa qualitativa[83];
— **Holanda:** quatro estudos de caso (artigos originais primários) de pesquisa qualitativa[36,30,84,41] e uma revisão sistemática[49];
— **Índia:** uma revisão sistemática[39];
— **Iran:** uma revisão sistemática[39] e uma revisão não-sistemática da literatura[59];
— **Irlanda:** um estudo de caso (artigo original primário) de pesquisa qualitativa[85];
— **Israel:** um estudo de caso (artigo original primário) de pesquisa qualitativa[86] e um de métodos mistos[34];
— **Itália:** uma revisão sistemática[40] e um estudo de caso (artigo original primário) de pesquisa qualitativa[30];
— **Nova Zelândia:** duas revisões sistemáticas[49,] e um estudo de caso (artigo original primário) de pesquisa qualitativa[75];
— **Noruega:** dois estudos de caso (artigos originais primários) de pesquisa qualitativa[30,75];
— **Organização Mundial da Saúde (OMS):** uma revisão não-sistemática de revisões sistemáticas[87];
— **Peru:** uma revisão sistemática[88];
— **Quênia:** uma revisão sistemática[88];
— **Rede de ATS da União Europeia (EUnetHTA):** dois estudos de caso (artigos originais primários) de pesquisa qualitativa[89] e de métodos mistos[90];
— **Reino Unido:** doze estudos de caso (artigos originais primários) de pesquisa qualitativa[91,92,30,67,93,60,94,75,95,96,97] e três de métodos mistos[98,44,34], quatro revisões sistemáticas[39,49,56,40],duas revisões não-sistemáticas da literatura[59,46] e um relatório de ATS[27];
— **Suécia:** dois estudos de caso (artigos originais primários) de pesquisa qualitativa[94,75];
— **Taiwan:** um estudo de caso (artigo original primário) de métodos mistos[31];
— **Todos os Países:** dois estudos de caso (artigos originais primários) de pesquisa qualitativa[35,99], uma revisão narrativa da literatura[100];

— **Uganda:** uma revisão sistemática[88];
— **Zimbábue:** uma revisão sistemática[88].

4.3 Achados dos Estudos

Os achados desta síntese de evidências qualitativas sobre modelos e métodos de participação social em ATS foram organizados para apresentação, conforme os critérios GRADE-CERQual de relato de achados[6,7] nas seguintes tabelas:

a. Tabela 2 – Tabela de Achados sobre Participação Social em Organizações / Agências promotoras de ATS por País (pg.17);
b. Tabela 3 – Tabela de Achados Específicos sobre Modelos de Participação Social por País (pg.35);
c. Tabela 4 – Tabela de Achados Específicos de Experiências sobre Modelos de Participação Social em Processos de ATS e Etapas Anteriores (Formulação de Políticas, Desenvolvimento) e Posteriores (Implementação e Monitoramento) de (Novas) Tecnologias em Saúde (pg.49).

Sua leitura deve seguir a observação sobre quais são os modelos de sistemas de saúde existentes em cada país para que seja possível quaisquer comparações com o sistema de saúde brasileiro para o qual se objetiva a tomada de decisão informada a partir desta síntese de evidências qualitativas para a implementação de um modelo (e métodos) de participação social em ATS e decisões sobre cobertura, na perspectiva da CONITEC/DGITS/SCTIE/MS.

Ressaltamos que, embora existam lógicas de engajamento social, desde a mais hierarquizada (informação) até a mais integrativa (participação), e diferentes métodos, nosso objetivo foi tentar oferecer subsídios para a construção de um modelo de processos mais participativos, nos quais diferentes métodos podem ser usados. Portanto, ressaltamos que os processos serão efetivamente participativos, se os métodos forem usados adequada e refletidamente. Do contrário, teremos apenas a impressão de um processo participativo (do inglês, *tokenismo*[14,19,26,27]).

Tabela 2 – Tabela de Achados sobre Participação Social em Organizações / Agências promotoras de ATS por País

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
Australia	**Pharmaceutical Benefits Advisory Committee (PBAC)**	**Technologies Identification**	Consultation	Online forms	• Patients • Public	National	Medicines submitted for approval for reimbursement	40,70,46
		Topic Selection/ Prioritisation/ HTA Scoping/ Framing	Consultation		Consumer representatives			
		HTA Undertaking	Participation	Committee	Patients			
		HTA Results Revision/ Formulating Recommendations	Participation	Committee	Patients			
		Recommendations/ Decisions Implementation	Participation	Appeal decision	Patients			
			Consultation	• Committee member representation • Brief patient group submission (template) • Detailed consumer impact statements	• Patients • Public			
		Disseminating HTA Findings/ Recommendations	Consultation	Website	Patient			
	Medical Services Advisory Committee	**HTA Undertaking**	Participation	Forum	Patients	National		40,41
		HTA Results Revision/ Formulating Recommendations		Committee	Patients			
			Consultation	Online	• Patients • Patient Groups			
Belgium	**Belgian Healthcare Knowledge Centre (*Federaal Kenniscentrum*, KCE)**	**Recommendations/ Decisions Implementation**	Consultation	Micro-economic grounded discrete choice experiments	Citizens	National	Medicines submitted for approval for reimbursement	93

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
Benin	**Health Technology Management by Ministry of Health**	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Participation	• Interviews; • Questionnaires	Public	National		72
		Conducting/ Commissioning Evidence-Based Analysis		Focus groups				
Canada	**Canadian Agency for Drugs and Technology in Health (CADTH)**	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Information	Online	Public	National		101,77
	Canadian Expert Drug Advisory Committee (CEDAC)	**HTA Results Revision/ Formulating Recommendations**	Participation	Appeal	Industry			
			Information	Online	Public			
	***Agence d'Évaluation des Technologies et des Mode d'Intervention en Santé (AETMIS)* of the Quebec Government**	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	Survey	Stakeholders	Regional		
		HTA Results Revision/ Formulating Recommendations	Information	Online	Public			
	Alberta Health & Wellness Executive Committee	**Technologies Identification**	Information	Online	• Public • Patients	Regional		40
		Topic Selection/ Prioritisation/ HTA Scoping/ Framing						
	Policy Advisory Committee of Cancer Care Ontario (PAC-CCO) – Drug Quality and Therapeutics Committee (DQTC)	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Participation	Committee representatives	Community	Regional		101,77
	Ontario Health Technology Advisory Committee (OHTAC)	**Technologies Identification**	Information	Website description of topic selection process	Public	Regional	Five technologies reviewed: • Colorectal cancer	74,40,25, 101,77

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
		Consultation	• Polling • Surveys			screening; • Percutaneous Aortic Value Replacement (PAVR); • Breast cancer screening for average and high risk women; • Gene expression profiling (GEP); • Serologic testing for celiac disease.	
		Consultation	• Horizon scanning: analysis of traditional and social media data, focus groups, surveys; • Delphi (every 2/3 years)	• Patients • Patient organizations			
		Participation	• Stakeholder meetings; • Advisory committee representation	Patients			
	Topic Selection/ Prioritisation/ HTA Scoping/ Framing	Consultation	• Vignette; • Citizen reference panel on health technologies report (on deliberation); • Invited submissions (targeted/web) • Social media analysis • Interviews • Focus groups	• Patient organizations			
		Participation	Committee representation (e.g., expert panel)	• Patients			
	HTA Undertaking	Information	• Post draft report on website; • Use social media to profile selected reports	• Public • Patients • Patient organizations			
		Consultation	• Lay review of plain language summary; • Solicited reviews of draft report	• Patient organizations			
		Participation	• Face-to-face meetings with high-priority groups; • Committee representation (e.g., expert panels)	Patients			

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
			• Citizen panels for high-priority topics (triggered by decision determinants framework)	Public			
	Conducting/ Commissioning Evidence-Based Analysis	Consultation	• Invited submissions; • Surveys; • Social media analysis; • Primary qualitative research/ synthesis	• Patients • Patient organizations			
		Participation	• Committee representation (e.g., expert panel)	Patients			
	HTA Results Revision/ Formulating Recommendations	Information	Online	Public			
		Consultation	Expert panel consultation with priority populations	Patients			
		Participation	Explicit discussion of how social/patient values were considered in review (meeting)	• Patients • Public			
	Recommendations/ Decisions Implementation	Information	• Web posting of public comments; • Relevant actions taken	Public			
		Consultation	• Online survey; • Citizen panel; • Provincial health technology advisory committee;				
		Participation	Face-to-face meetings to discuss/address concerns				

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
		Disseminating HTA Findings/ Recommendations	Information	• Multimedia dissemination of OHTAC report; • Lay review of plain language summary; • Targeted dissemination to high-priority groups	• Public • Patients • Patient organizations			
	Toronto's Health Policy Citizen Council	**HTA Undertaking**	Participation	Committee membership	Public	Regional		40,54
		Conducting/ Commissioning Evidence-Based Analysis	Consultation	Written/oral testaments	Patients			
		HTA Results Revision/ Formulating Recommendations	Consultation	• Review reports; • Draft recommendations	Public			
Denmark	**Danish Board of Technology (Danish Parliament)**	**HTA Undertaking**	Consultation	Consensus conferences	Public	National		89
		Disseminating HTA Findings/ Recommendations	Information	Results of public deliberations to decision makers and the public				
Finland	**Finnish Office for Health Technology Assessment (FinOHTA)**	**Conducting/ Commissioning Evidence-Based Analysis**	Information	Rapid reviews	Stakeholders	National		68
		Recommendations/ Decisions Implementation		Newsletters, communications media				
France	**Ministry for Health and Social Security**	**Technologies Identification**	Consultation	• Technologies may be referred by patient and/or carer organizations	Patients	National		40
		Topic Selection/ Prioritisation/ HTA Scoping/ Framing	Participation	• Patient representatives may participate in defining the scope of the HTA	Patients	National		

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
	HTA Undertaking	Participation	• Patient representatives may participate in defining the scope of the HTA	• Public; • Patient	National		
	HTA Results Revision/ Formulating Recommendations	Consultation	• Patient representatives may provide comments on report and draft recommendations	Patient	National		
	Recommendations/ Decisions Implementation	Consultation	• If the 'applicant' is a patient or carer organization, he/she may appeal the decision	Patient	National		
French National Authority for Health	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	• Patient representatives may participate in consultations during the HTA	Patients	National		
	HTA Undertaking	Consultation	• Patient representatives may provide comments on draft protocol; • Patient representatives may submit information to group preparing HTA	• Public; • Patients	National		
	HTA Results Revision/ Formulating Recommendations	Participation	• Patient representatives may participate in working groups/committees (includes patient representative)	Patients	National		
Haute Autorité de Santé	**Conducting/ Commissioning Evidence-Based Analysis**	Consultation	• Online consultation; • Focus groups	Public	National		41,58
	HTA Results Revision/ Formulating Recommendations	Participation	• Committee	Patient representative	National		

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
		Disseminating HTA Findings/ Recommendations	Information	• Online publication	Public	National		
Germany	**Institute for Quality and Efficiency in Health Care (IQWiG)**	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	Online topic suggestion	• Patients • Consumers	National	• Addresses a question relevant to patient action, decision or critical knowledge;	102
		Conducting/ Commissioning Evidence-Based Analysis	Consultation	Online rating from eligible: • Systematic review; • HTA	• Patients • Consumers	National		
		Recommendations/ Decisions Implementation	Consultation	Analytic Hierarchy Process: • Written surveys; • Questionnaires	• Patients • Consumers • Health Professionals	National	Antidepressant treatment	65
	Gemeinsamer Bundesausschuss	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	Online topic suggestion	Patient representatives	National		41,58
		Conducting/ Commissioning Evidence-Based Analysis	Consultation	Online forms (one month)	• Patient representatives • Professional organisations			
		HTA Results Revision/ Formulating Recommendations	Information	Draft protocols/ reviews online for comment	Public			
			Participation	• Board meetings; • Technology appraisal committees	5 patient representatives			
		Disseminating HTA Findings/ Recommendations	Information	Online publication				
			Participation	In person press conference (after HTA is done) without voting right				
		Topic Selection/ Prioritisation/ HTA Scoping/ Framing	Consultation	Submit petitions	• Patients • Patient organisations • Carer organisations	National		40,46
			Participation	Defining scope of HTA				

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
		HTA Undertaking	Information	Online publication	• Patients • Public			
			Consultation	• Comments on draft protocol; • Submit information to group preparing the HTA				
		HTA Results Revision/ Formulating Recommendations	Consultation	Comment on draft assessment report/ preliminary recommendations				
			Participation	Committee (without voting rights)				
Netherlands	***College voor zorgverzekeringen* (CVZ)**	**Technologies Identification**	Consultation	Online forms	• Patient • Carer	National		58,40
		HTA Undertaking		HTA report	Public			
		HTA Results Revision/ Formulating Recommendations		Invitation to oral/ written statement	• Patients • Carer			
			Participation	Committee membership	• Decision-makers; • Patient associations			
New Zealand	**Pharmaceutical Management Agency of New Zealand (PHARMAC); Pharmacology and Therapeutics Advisory Committee (PTAC)**	**Technologies Identification**	Consultation	Technologies' referral	• Patients • Public	National		40
		HTA Undertaking		Submit information to group preparing evaluation report (PHARMAC)	• Patient representatives • Carer representatives			
		HTA Results Revision/ Formulating Recommendations		Comments on evaluation report from affected parties (PTAC)				
Sweden	**County Councils**	**HTA Results Revision/ Formulating Recommendations**	Participation	Deliberative dialogues	Citizens	National		97
UK	**National Institute for Health and Care**	**Technologies Identification**	Consultation	Technology referral	Public	National		40,58,41

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
Excellence (NICE)	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	• Written comments; • Multi-stakeholder workshops	• Public • Patients • Carers • Voluntary organizations • Charities			
		Participation	Topic selection panel	• Patient representatives • Carer representatives			
	HTA Undertaking	Consultation	Submit information to group preparing HTA	• Patient organisations • Carer organisations			
		Participation	Scope definition				
	Conducting/ Commissioning Evidence-Based Analysis	Consultation	Colloquial evidence	• Experts (professionals/ clinicians) • Patients • Carers • Grey literature • All stakeholders			
			• Written evidence submissions; • Personal testimony	• Public; • Patient organisations • Carer organisations • Voluntary organisations • Charities			
	HTA Results Revision/ Formulating Recommendations	Consultation	• Comment on report and draft recommendations;	• Public • Patient organisations • Carer organisations			
		Participation	Decision-making committees and advisory groups	Partners' Council (Lay members - min 2, often 3, sometimes 6)			
			Oral testimony to committee meeting	Clinical/patient experts			

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
			Deliberative assembly (parts of committee meetings)	Citizens' Council (Public, patient organisations, carer organisations)			
	Recommendations/ Decisions Implementation	Consultation	Appeal recommendations	• Public • Patient organisations • Carer organisations			
	Disseminating HTA Findings/ Recommendations	Information	Online publication of guidance	• Public; • Patient			
National Institute Health Research Health Technology Assessment Programme	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**	Consultation	Online form (topic suggestion)	• Public • Patients	National		41
		Participation	• Representatives on boards or panels • Soliciting 'public reviewers'				
Scottish Medicine Consortium (SMC)	**HTA Undertaking**	Consultation	SMC Patient and Public Involvement Group (three members of general public) ensures perspective in all SMC assessments	• Patients • Public	National		41,40
	Conducting/ Commissioning Evidence-Based Analysis	Consultation	Written evidence (Patient Interest Group Submission)	• Voluntary groups; • Health charities			
	HTA Results Revision/ Formulating Recommendations	Participation	Patient Interest Group Submission present at consortium committee (monthly) meetings	Public (3 members)			
NHS Clinical Commissioning Groups (CCGs) and Primary Care Trusts (PCTs)	**Recommendations/ Decisions Implementation**	Information	• Online publication; • Local distribution	Public	Local		103
		Consultation	• Online survey; • Focus groups; • Road shows				

Social Participation in HTA Agencies		HTA Process Stages	Model	Method	Population	Level	Technologies	References
			Participation	• Public meetings; • debates				
	All Wales NA Medicines Strategy Group (Decisions)	**HTA Undertaking**	Consultation	Submit information to group preparing HTA	• Patient organisations • Carer organizations	National		40
		HTA Results Revision/ Formulating Recommendations		Comments on report and draft recommendations				
			Participation	Committee meetings held in public				
USA	**Washington State Health Technology Assessment Program**	**Technologies Identification**	Consultation	Currently developing a process for input	Public	Regional		41
		Topic Selection/ Prioritisation/ HTA Scoping/ Framing		Comment proposed and final topic selections (30 days)				
		Conducting/ Commissioning Evidence-Based Analysis		• Contribution to evidence reviews; • Evidence submission (30 days after selection announcement)				
		HTA Results Revision/ Formulating Recommendations		Comment on draft reports (30 days)				
	Washington State Healthcare Authority Health Technology Clinical Committee	**Technologies Identification**	Consultation	Technologies referral	All	Regional		40
		HTA Undertaking		Information submission to group preparing HTA				
		HTA Results Revision/ Formulating Recommendations		Comments on report and draft recommendations				
			Participation	Committee meetings held in public				
	Centres for Medicare and Medicaid Services	**Technologies Identification**	Consultation	Technologies referral	• Patients • Carers	National		

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
(CMS) - Medicare Evidence Development and Coverage Advisory Committee	**Topic Selection/ Prioritisation/ HTA Scoping/ Framing**		Additional information/ comment on potential technology topics identified by CMS staff	All			
	HTA Undertaking		Information submission to group preparing HTA				
	HTA Results Revision/ Formulating Recommendations		Register to present to committee meeting				
	Recommendations/ Decisions Implementation		Appeal recommendations				
State of Oregon Health Resources Commission	**Technologies Identification**	Consultation	Technologies referral	All	Regional		
	HTA Undertaking		Information submission to group preparing HTA				
	HTA Results Revision/ Formulating Recommendations		• Register to present to committee meeting; • Comment on report and draft recommendations				
		Participation	Committee meetings				
Barriers: **• More HTA requests than resources to complete them;** **• Policy-makers refining their their HTA strategies should clearly articulate the goals of their public involvement efforts (e.g., legitimacy, instrumental, educative) to then proceed to select and fashion public involvement methods that will fulfil these goals, as well as demonstrate how public contributions were used to shape decisions;** **• Political (efforts to democratize health policy making through greater public involvement have been staunchly resisted in favour of technocratic (i.e., expert-driven) approaches) and technical challenges (opting for careful design over the 'quick fix' requires organizational resources (e.g., dedicated and qualified personnel to design, implement and link public involvement input to decision-making) that even the most committed decision makers have difficulty justifying).** Facilitators: **• Public to guide funding decisions** **• Working with affiliated organisations leads to better suggestions.**							101,77
Barriers: **• Use of HTA website for topic suggestions requires knowledge of the opportunity, which is unlikely;** **• How to select from large number of voluntary organizations/ charities/ patient groups for consultation;**							74

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
• Balancing broad public/patient interests with narrower interests of organizational representatives; **• Difficult to translate the problems of people's daily lives into a topic that supports a well-structured research question;** **• Constraints imposed by HTA program and internal procedures.** Facilitators: **• Factors that shape the impacts of social participation strategies in HTA such as the interactions between citizen deliberators and expert advisory committees, the clarity of citizen roles in relation to the HTA advisory process, and the tenuous nature of citizen-expert relationships, which are embedded within broader political processes must be considered before choosing a social participation model and methods for each model type;** **• Design concerns of deliberative participatory structures must consider how to maintain the independence and credibility of the citizens' panel while ensuring that it contributes substantively, preventing a "token" role for citizens in citizens' juries and/or panels or even being ignored by the expert body to which they report;** **• Adequate "expertise space" that values citizens' lay knowledge so they believe they can contribute in a significant way to highly technical debates - achieved by: a) framing issues to focus the deliberation on social and ethical dilemmas (instead of technical issues); b) providing easily-accessible background information; c) providing an inclusive style of facilitation that highlights the original contributions citizens are able to make based on their values and experiential knowledge.**						
Facilitators: **• It is important to foster transparency and feedback via evaluation of social participation activities regarding participants' perceptions around how consultation impacted on decisions relating to clinical governance and on local service developments;** **• It is important to evaluate information strategies outcomes by measuring the level of awareness of all stakeholders about the information published by HTA Organisations/ Sponsors.**							103
Barriers: **• Even where processes for stakeholder engagement in priority setting exist, a considerable part of prioritization will always occur within a "black box" inside an agency, or involving competing subject areas where no identifiable practical proxy for affected communities is available.** Facilitators: **• Meaningful citizen/consumer qua patient (and their families, carers, legal representatives) as well as advocates engagement in decision-making and priority-setting for HTA and coverage processes requires well-networked stakeholders who are then provided with information, resources, and support and engaged in repeated facilitated debate;** **• Interest for the public is a relevant priority-setting criterion for some HTA agencies;** **• It is important to consult with experts such as patient or consumer representatives as this could provide HTA Organisations/ Sponsors with a measure of the extent to which they have achieved the goal of providing information that is interesting to patients and consumers.**							102
Barriers: **• Institutional framework in which HTA is conducted may importantly influence the decision-making process and stakeholder involvement by HTA Organisations/ Sponsors;** **• Other forces (e.g., social pressure) may also influence the decision-making process of policy makers and organisations supporting their action, including HTA Organisations/ Sponsors - these forces are, at least partially, independent of the institutional framework and may strengthen or counterbalance the impact of this framework on the decision-making process;** **• The importance of the institutional framework highlights the fact that successfully transferring a model of stakeholder involvement from one country to another would be very complicated unless the two countries share the same administrative approach and, possibly, the same HTA organisational procedures/engagement strategies.**							58
Barriers: **• While citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates should be involved in HTA to some degree and at different stages of an assessment and the resulting decision-making processes, Analytic Hierarchy Process (or another multiple-criteria decision analysis method) would most likely be restricted to situations where a quantification of citizen/consumer/patient preferences can precede or be directly integrated into the HTA and its results, for example, by selecting, prioritising, or weighting patient-relevant endpoints of treatment.** Facilitators: **• Well-networked citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates who are then provided with information, resources, and support and engaged in repeated facilitated debate**							65
Barriers:							41

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
• Citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates may be frustrated by past engagement efforts which they may not feel have meaningfully influenced policymaking. They may not perceive value in being engaged in HTA; • They may have limited literacy skills or knowledge preventing them from engaging meaningfully in HTA-related capacity building; • They may be unaware of the existence of the HTA agency and its link to coverage decisions regarding health technologies. • Citizens'/consumers' qua patients' (and their families, carers, legal representatives) as well as advocates' organisations may be reluctant to join a network that can be called upon to contribute to the HTA process because it may be perceived as a threat to their independence; • HTA practitioners (i.e., people producing HTAs or making recommendations) may face difficulties in developing a shared vision for social engagement in HTA; • Some practitioners may be unwilling to participate in developing or implementing new practices that could challenge their professional authority and resources; • Some practitioners may grapple with the tensions between a traditional focus on clinical and economic evidence and pressures to incorporate patient/social values input; • Some practitioners may perceive that engaging the public and patients will politicise what should be a 'neutral' evidence informed process; • Some practitioners may challenge the robustness of social/patient values as a valid source of evidence; • Some practitioners may believe that the public and patients are unable to contribute meaningfully; • Some practitioners may grapple with prevalent and persistent misconceptions about what 'social engagement' means; • Some practitioners may not be inclined to obtain additional training without tangible incentives; • Some practitioners may not perceive value in engaging with society; • Some organisational leaders may worry that engaging citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates and their groups could threaten their scientific credibility and political autonomy; • Some organisational leaders may worry that social engagement could slow down and increase the complexity of current processes; • Organisational leaders may face difficulties in developing a shared vision for social engagement given their constraints and competing priorities; • Some HTA agencies may lack the time, resource and expertise required to support high-quality social engagement; • Some organisational leaders may be unwilling or uninterested in making long-term sustainable financial commitments towards building HTA practitioners' capacities due to budget uncertainties for their existing programs and services; • Some organisational leaders may not see value in investing heavily in education and training, especially those with frequent staff turnover and limited resources; • Some organisational leaders may lack the capacity to coordinate consistent educational content and activities; • Some HTA agencies may lack the knowledge/skills to engage with particular populations (e.g., Ontario's First Nations populations) or the infrastructure to engage particular groups (e.g., hearing-impaired patients); • Some HTA agencies may lack champions or agents of change necessary to adopt and sustain social engagement innovations. • Some organisational leaders may be unwilling or uninterested in making long term sustainable financial commitments towards building the public's and patients' capacities due to budget uncertainties for their existing programs and services; • Some organisational leaders may have difficulty with multi-organisational initiatives that are subject to changes outside their control; • Some organisational leaders may have difficulty ensuring that educational activities reach all those who could benefit, including hard-to-reach groups; • Some organisational leaders may be reluctant to collaborate with patient or consumer groups, which may have strongly held beliefs inconsistent with research evidence. • Some policymakers may worry that social engagement could slow down and increase the complexity of current processes; • Some health-system stakeholders may challenge engagement efforts on the grounds that they are not representative of a country's diverse population (e.g., place of residence, race, ethnicity, culture, occupation, gender, religion, educational level, socioeconomic status, and level of social capital/social exclusion). Facilitators: • Health Quality Ontario is currently developing a corporate social engagement strategy to increase collaborations with the public, patients and their families across all their activities; • Various health-system stakeholders are engaged in social engagement activities in Ontario, which illustrates that people within and outside of the government are paying serious attention to this issue; • The Ontario Citizens' Council was established in 2009 to provide advice regarding the needs, culture and attitudes of Ontario's citizens about government drug policy; • The Change Foundation recently launched its PANORAMA project, a provincial advisory panel comprised of healthcare users and caregivers;							

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
• The Ontario Drug Policy Research Network, a province-wide network of researchers providing drug policy-relevant research to decision-makers, is currently involved in various social engagement efforts (e.g., implementing citizen panels and interacting with Ontario Citizens' Council); **• The McMaster Health Forum recently launched a citizen-panel program to provide the opportunity for citizens to share their views and experiences on high-priority issues;** **• There are opportunities to learn from HTA agencies in other jurisdictions that have extensive social engagement experiences (some of which are currently evaluating their practices and can serve as models for consideration within the Ontario context);** **• There is also an opportunity to build on past and ongoing initiatives of the HTAi Interest Sub-Group on Patient and Citizen Involvement in HTA, which constitutes a vibrant international community of practice dedicated to the issue;** **• The Canadian Foundation for Healthcare Improvement has established a collaborative initiative entitled Partnering with Patients and Families for Quality Improvement, which provides funding, coaching and other support for Canadian healthcare organizations that engage patients and families in designing, delivering and evaluating healthcare services;** **• There is an opportunity to build on ongoing efforts to develop coalitions of patient organizations, such as Patients Involved in NICE, the Cochrane Consumer Network, or B.C. Patients as Partners-Patient Voices Network (currently on hold);** **• There is an opportunity to build on ongoing efforts to develop training opportunities for citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates and their groups, such as the training offered by NICE, the online educational training program developed for patient advocates – eMEET (Medicine Evaluation Educational Training) developed by Eli Lilly (a pharmaceutical company) and endorsed by HTAi, or other training opportunities like those offered by the department of collaboration and patient partnership at the *Université de Montréal*, or the European Patients' Academy.**						
Barriers: **• Deliberative process creates incremental and slow changes in the system;** **• Immediate impact of the Health Parliament: despite a statement of official endorsement of the Health Parliament initiative by the Health Council, it did not show any interest in continuing the initiative as part of its own activities, and funds obtained privately to continue the initiative were not sufficient to ensure its continuity;** **• Health Parliament participants expressed both scepticism and hopes that their recommendations would be accepted and have a direct impact on the healthcare system;** **• This realisation may also indicate that the deliberative process may have served to co-opt participants' views and prompt them to adopt the dominant stakeholders' perspective – the fact that the summaries and recommendations of the Health Parliament included diverse views may alleviate some of the concern regarding co-optation.** Facilitators: **• General impact on the system: the professional consultants to the regional groups reported that their involvement in the Health Parliament had sensitized them to the importance of soliciting citizens' views and considerations;** **• The initiative inspired two of the largest health fund directors to implement their own public deliberative initiatives;** **• The deliberative process got participants to think about the policy issue beyond their individual perspective, contradicting the contention of some critics of public deliberative forums that people will mainly base their views on personal interest;** **• Participants said they learned to realize the difficulties involved in making healthcare policy decisions ["We came to realize and appreciate the difficult ethical and moral problems the healthcare system faces, and to understand why the heads of the system thought it appropriate to bring these problems to public consultation"].**							89
Barriers: **• Policymakers, planners and administrators at the MoH were collectively regarded as the actor group most empowered to solve health technology management problems;** **• Unwillingness and self-interested attitudes of policymakers to engage in HTA problems and the high degree of politicisation influencing public sector decision-making;** **• High-level corruption in health technology management processes.**							72
Barriers: **• Open (public) committee meetings: public and patient representatives expressed discomfort in expressing their views in public (fear that their views may not always align entirely with the public);** **• Lack of resources available to patient organizations to assist them in completing submissions: many patient/carer organizations are not adequately resourced to make submissions (only large, well-funded (often by industry) groups may be able to submit) – potential biases in the information presented;** **• Inability for individual patients to provide information: some coverage decision-making processes only accept patient input through a patient/carer organization (they must identify an appropriate organization and hope that the organization is willing to make such a submission);**							40

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
• Lack of awareness of the coverage decision-making process and opportunities for patient or public input: patients and the public are often unaware of options for contributing their views; **• Ability of patients to submit product-specific impact statements: some processes restrict the content of patient impact statements to the condition or disease;** **• Lack of participation from patient or public representatives on committees;** **• Legal and regulatory constraints associated with communication to patients would need to be considered in many jurisdictions.** Facilitators: **• Training of patient or public representatives: ensure that patient or public representatives feel able to contribute meaningfully to discussions (need for educational opportunities that introduce them to basic terms, concepts and policy options);** **• Proposals to facilitate submissions by any organization: prepare training materials; hold workshops; appoint a dedicated liaison officer to assist groups with submissions; offer grants to such organizations; submissions should include declarations of conflicts of interest;** **• Healthcare organizations should engage in outreach activities to educate patients and the public (information on coverage decision-making processes, the roles of patient and the public);** **• Push towards Patient-Reported Outcomes (PROs): impact statements should be able to include patients' experiences with the proposed technology;** **• Encourage active participation from patient or public representatives (they should be given an explicit task, such as summarising any input collected from patient/carer organizations).** **• Adequate (tailored) public/ patient advocacy groups education programs** **• Ensure that views presented within HTA decision-making process are not biased or overrepresented;** **• Presentation of written or oral testaments from patients ('consumer impact statements') either by committee invitation (e.g., Australia France, Germany or The Netherlands) or at the request of the patient/carer or patient/carer organization (e.g., the UK);** **• Broader participation through citizen juries, deliberative forums;** **• Feedback;** **• Transparency;** **• Flexibility;** **• Social media.**							
Facilitators: **• The perspectives of patients are being increasingly taken into account as regulatory authorities begin to rely on studies that document the benefit-risk trade-off from the perspective of patients;** **• European developments show that the idea of patient participation is playing an increasingly important role;** **• Currently, a paradigm shift is taking place where citizens no longer act as merely passive players in the health sector, but increasingly interact as partners with regulatory authorities;** **• The range of participation efforts extends from qualitative surveys of patients' needs to approaches of science-based documentation of quantitative patient preferences, for example, on the national level, such as IQWiG's pilot studies on preference elicitation in Germany or the KCE initiatives in Belgium, as well as on the European level as in the IMI-PROTECT studies and the EMA VALUE study;** **• The commonality of all approaches is that the patient benefit is seen as a multidimensional construct, and assessment requires the involvement of affected patients to supplement trial data;** **• As a one-dimensional indicator for the explanation of (choice) decisions, patient preferences represent the extent of desirability or undesirability of a characteristic of a product;** **• As European pilot projects have shown, modelling of the benefit-risk assessment for medicines is possible, but more research projects are needed to design the tools that are accessible to patients and other stakeholders, appropriate to the needs of the regulators/assessors, and that can be integrated into the current processes in benefit-risk evaluation;** **• Piloting might take some time because development of the methodology of benefit-risk assessment requires collaboration of many different stakeholders across the EU;** **• Quantitative, systematic, and patient-focused approaches will very likely support regulatory decisions on approval of health technologies in the future.**							93

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
Barriers: **• Use of HTA website for topic suggestions requires knowledge of the opportunity, which is unlikely;** **• How to select from large number of voluntary organizations/ charities/ patient groups for consultation;** **• Balancing broad public/patient interests with narrower interests of organizational representatives;** **• Difficult to translate the problems of people's daily lives into a topic that supports a well-structured research question;** **• Constraints imposed by HTA program and internal procedures.** Facilitators: **Working with affiliated organizations leads to better suggestions.**							25
Barriers: **• Active consumer and community participation in health care are based on subject's locus of control (e.g. personal or social) or on the nature of the barrier (e.g. risks or costs);** **• In Australia, the NHMRC has drawn up a list of barriers to effective consumer and community participation including: lack of infrastructure support of organisations; lack of skills or confidence in organisations; skills deficits in consumers; insufficient opportunity for vulnerable groups for input; weak links between providers of health information and recipients; and disseminating information without consumer input;** **• A series of specific challenges to consumer engagement, including stigma, language and cultural differences were also identified;** **• The NHMRC's conclusions are supported by other international studies which found similar barriers to consumer and community engagement in the health system planning, provision, reform and research;** **• Time factors and geographic distance are commonly identified as adding to the difficulties in engaging consumers;** **• Consumer literacy – both health and general, further complicates the process;** **• At least one study identified physical and psychological exhaustion of involvement as a barrier to the engagement of some people with disabilities;** **• Facilitating consumer and community engagement, as well as patients' participation, can impose a financial burden on health care systems;** **• While tools such as electronic personal health records are reported to be effective in enhancing patients' participation, their implementation could add substantial costs;** **• Several reviews have identified budget limitations as a barrier to consumer and community engagement;** **• Consumer-led services could be effective and useful, but they are still underfunded;** **• Funding is one of the challenges of community-engaged research;** **• Despite supportive legislation and growing efforts in the UK, there remains a need for financial and other incentives in order to promote participation;** **• The financial cost of participation has been raised as a specific barrier (along with physical demands) for people with disabilities;** **• Limitations of participation methods: representatives might find it difficult to talk in public, and may require training; consumer organisations usually do not have adequate funding to compete with organisations that are supported by industry; in some engagement processes, input is taken from representative organisations rather than individual consumers; some consumers are not aware of the possibility of providing inputs; at times, the impact or role of consumers may be limited; although consumer representatives may be present in committees, they might be not be actively involved in the processes;** **• Structural issues: successful implementation of consumer and community engagement requires regulation and organisational support;** **• Structural issues, such as "fee for service" health care delivery have been implicated in resistance to shared decision-making, which is considered to be time consuming;** **• Condition-specific limitations: for some psychiatric patients, the stigma attaching to some conditions may also be a barrier to participation in health care;** **• One of the barriers to participation in HIV research is HIV-related stigma;** **• Population-specific limitations: people's preference for involvement in decision making is dependent on characteristics such as age, educational level, disabilities and ethnic and cultural backgrounds – an individual's preference for engagement might change over time or be based on changing circumstances;** **• Children and adolescents face specific difficulties in consumer and community engagement, such as parental consent, as was the case in one study of adolescents' participation in HIV prevention research;** **• There are challenges in gathering and synthesising consumers' viewpoints, and there is often not enough evidence to compare different methods of consumer and community engagement in order to adequately judge which approach is most likely to be effective.** Facilitators: **• For vulnerable indigenous populations, additional factors were identified as contributing positively to the engagement process;**							54

Social Participation in HTA Agencies	HTA Process Stages	Model	Method	Population	Level	Technologies	References
• Facilitators of consumer and community engagement in these vulnerable populations included: widespread community involvement; an explicit focus on the indigenous population as a whole and high risk individuals in particular; the use of indigenous health workers; and regular contact with participants; **• Preparedness: attitudinal or behavioural changes might be needed on the part of both consumers and professionals. Hibbard et al. have suggested that those advocating consumer and community engagement might be pressing both consumers and health professionals to adopt new roles;** **• Health care professionals' factors that could affect consumer and community engagement: the desire to maintain control; time limitations; and personal beliefs;** **• Consumers' factors that could affect consumer and community engagement: acceptance of a new role; lack of knowledge and confidence; and socio demographic parameters;** **• Need for training researchers involved in community based research;** **• Adequate communication, financial and logistical support;** **• Adequate; • Collaboration with consumer organisations; and keeping the project at a manageable scale;** **• It is important to carefully evaluating initiatives for consumer and community engagement before commencing implementation;** **• It is useful to take baseline measures, and estimate and evaluate the costs, benefits, barriers and facilitators of each engagement initiative;** **• While seeking to foster long-term benefits, consumer and community engagement is likely to require immediate allocation of resources;** **• Need to undertake a comprehensive approach to assessment, including evaluating hidden costs such as training of health care professionals and consumers, and time required for the participation process as well as that allocated for meetings or presentations;** **• The costs of such initiatives have to be compared with the benefits of consumer and community engagement for consumers, the community and the health care system;** **• Proposed benefits include enhanced ownership and empowerment of consumers, and increased accountability of initiatives;** **• To ensure the analysis is comprehensive and rigorous, the viewpoints of different groups of stakeholders must be included;** **• This needs to be supported by precisely defined roles and responsibilities and the involvement of consumers in all health information-related steps: planning; development; evaluation; and dissemination.**							
Facilitators: **Implementation considerations:** **• Problems with applying technical information and national recommendations to local decision-making can be reduced if there are formal links between the producers and users of HTA;** **• Learning through collaboration and exchange of experience can help to overcome those institutional and capacity barriers that often hinder implementation.**							68

Tabela 3 – Tabela de Achados Específicos sobre Modelos de Participação Social por País

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
ALL COUNTRIES			
For health technology development, assessment and implementation/monitoring processes, all three models of social participation (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented with an additional aim to include the widest range of their national population as possible from a global perspective, at all levels (directed, local, national and regional).	(35,100,99)	High confidence	No concerns for all CERQual components.
AFRICA			
All three types of social engagement are used. Social engagement is promoted at the national level and for HTA matters.	(39)	High confidence	Minor concerns regarding adequacy of data (no specific data extracted that could build this finding for each country in Africa).
Initiatives favour marginalized and disadvantaged groups, aiming at empowering them. Hence the utilization of community-based participatory research, which bridges the gap between research and practice and aims at eliminating disparities in population health. By drawing on communitarian or tribal structures, it is possible to guarantee the post-intervention sustainability of initiatives. In this way, three results can be obtained: empowerment of patients, improved social networking, and the dissemination of self-efficacy skills.	(39)	High confidence	Minor concerns regarding coherence (review does not address barriers).
AUSTRALIA			
For health technology assessment, policy/decision-making and health technology development processes, all three models of social engagement (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented around Australia with an additional aim to include the widest range of their national population as possible. Trust in Australian decision makers has been eroding for some time also in healthcare. Recently, to regain some of this trust, Australian HTA organisations started developing and implementing social engagement initiatives that are guided by a framework of social values or desirable social engagement acceptance criteria that is both committed to transparency, representativeness, clarity (what is actually wanted from the public), influence (how the outputs will be incorporated into policy and decision-making), independence and early engagement.	(49,40,104,40,15,61,59,60)	High Confidence	Minor concerns regarding methodological limitations (lack of reviewers' reflexivity as we cannot tell if researchers collecting data were also the health professionals delivering care, which could contribute to biased data collection).
BANGLADESH			
Initiatives pertaining to HTA are promoted at the national level. The three types of engagement are used. This so because a comprehensive engagement of the community if sought, with the following outcomes: building of social capital, community capacity building, empowerment of community members, empowered and improved social networking, and self-efficacy skills for participants.	(39)	High confidence	Minor concerns regarding adequacy of data (no specific data extracted that could build this finding for Bangladesh).
BENIN			
Consultation is utilized, at the national level, for purposes of policy-making. This is done	(64)	High confidence	No concerns for all CERQual

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
by means of interviews, questionnaires, focus groups, and dialogue meetings. These initiatives were impaired by the attitudes of the HTA agency itself, whose decision-makers were not completely willing to understand the patients' needs, in addition to being likely to be get involved in corruption schemes. Facilitators to the process were: stimulation of mutual learning between stakeholders, development of a shared definition of problems and causes, and the joint formulation of possible solutions.			components.
BRAZIL			
Information, consultation, and participation are used at the national level, in the framework of policy-making. However, those processes are mobilized not by HTA agencies but in health-research. It was seen that the use of too narrow recruitment parameters constitutes an impediment to actual engagement. Facilitators were: reporting, evaluation of process and outcomes, flexibility in the design of citizen juries in order to adjust them to specific aims, accountability by decision-makers, and flexibility in the selection of analysis techniques.	(40)	High confidence	No concerns for all CERQual components.
CANADA			
For health technology assessment and policy/decision-making processes, all three models of social engagement (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented around Canada with an additional aim to include the widest range of their population as possible, especially at the national level. If we consider both development and implementation of social engagement methods as processes — i.e. soft/social technology — after the UK, Canada is the country where more financial, institutional and governmental investments have been made to promote and support social participation strategies sponsored by health professionals and technology assessment and policy/decision-makers and organisations. Sponsors provide funding, coaching and other support for Canadian healthcare organisations that engage citizens/consumers qua patients (and families) in designing, delivering and evaluating healthcare technologies, as well as more focused, purposeful participatory processes informed by evidence from their own or others' experiences by nurturing a climate conductive for social engagement (mobilizing the community, fostering respect and trust, developing an attitude shift for professionals and utilising a partnership — i.e. a citizen science — approach) and empowerment. Canadian HTA organisations started developing and implementing social engagement initiatives that prioritise the more encompassing approach proposed by the Participation Model rather than other Consultation strategies, because of experienced challenges with the various groups of social actors involved, namely: citizens/consumers qua patients and families/carers/legal representatives (frustration with past engagement efforts that may not have been meaningful in either engaging or influencing the debate due to limited literacy skills and/or knowledge, or due to unawareness of health technology assessment organisations and their link to coverage decisions regarding health technologies, or even lack of confidence in the transparency and legitimacy of such organisations' activities), health technology assessment practitioners (lack of	(53,49,65,40,38,73, 74,66,29,42,60,39,55,67,56,101, 69,28)	High confidence	No concerns for all CERQual components

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
incentives to attain a shared vision for the social engagement approach and unwillingness to participate in both development and implementation of social engagement initiatives that could challenge their professional authority and resources, also due to the perception that such activities will politicise what should be a 'neutral' evidence-informed process, shifting the traditional focus on robust clinical and economic evidence to incorporate social values and experiences input), health technology agencies (unwillingness or lack of interest, time resources and expertise in making long-term sustainable financial commitments towards building high-quality capacities for both HTA practitioners and citizens/consumers qua patients due to budget uncertainties for their existing programs and services, specially knowledge/skills and infrastructure to engage with particular multi-ethnic and hard-to-reach groups, besides fears of slowing down and increasing the complexity of current processes with frequent staff turnover and competing priorities), and health systems. Aiming to avoid such challenges in devising meaningful approaches to actively engage society in informed and increasingly politically charged debates about publicly funded goods such as health technologies and social services, the main recommendation from Canadian sponsors is to devise a combination of both Consultation and (direct) social Participation strategies to synergistically increase the citizens and consumers qua patients' influence on health professionals, technology assessment and policy/decision-makers and organisations, and, ultimately, health systems. In this sense, the Canadian experience is to improve participation strategies that are usually more relevant at both beginning and end of health technology assessment process; whereas Consultation methods have been more pertinent throughout the evaluation process. Nevertheless, various forms of engagement could be combined, such as limiting the collaboration of patients (and families/carers/legal representatives) with direct links to the health technology in question to certain stages of the process, while involving citizens'/consumers' qua patients' representatives as partners in the health technology development and/or assessment committee on a full-time basis. Ultimately, it is important to engage society as early as possible — not once a recommendation has been made – and evaluate social engagement practices to provide evidence to inform future initiatives for introducing the society's perspective in such processes and convincing managers of its relevance and utility.			
CHILE			
Information and consultation processes are used, at the national level, in the context of technology implementation and monitoring. The aim is not only to invite citizens to make informed choice but also to give them the means and conditions necessary for taking such informed choices.	(75)	Moderate confidence	Moderate concerns regarding adequacy of data (data comes mainly from one primary (case) study).
CHINA			
Information, consultation, and participation are used, at the national level, in the context of HTA. For so doing, the community-based participatory research approach (CBPR) is used, which requires a careful consideration for the research methodologies to be used. It is also crucial to have the most appropriate selection criteria, especially when it comes	(39)	High confidence	Minor concerns regarding adequacy of data (no specific data extracted that could build this finding for China).

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
to focusing on specific ethnic groups. If this is done, even "hard-to-reach" groups can be motivated.			
Engagement processes stress the position of disadvantaged and marginalized communities, because their material limitations often impair their role in engagement initiatives. The CBPR aims precisely at bridging the gap between research and practice through an equitable engagement of the community in order to eliminate disparities in population health by addressing power imbalances.	(39)	High confidence	Minor concerns regarding adequacy of data (no specific data extracted that could build this finding for China).
DENMARK			
Information, consultation, and participation processes are used, at the local and national level, in the context of HTA and technology implementation and monitoring. The design of the engagement process depends on the technology focused on, the agency's institutional context, the interests of the stakeholders involved, and the HTA community's ideas about the technology. The aim is to invite individuals to express viewpoints and choices (by means of free and informed processes), as well as to make citizens familiar with technologies. Engagement can happen in different ways: reception or dissemination of information; provision of data (the public provides data); commenting (from the public); collaboration (between agency and the public); engaging (the public receives some decision-making responsibilities), and controlling (the public controls the HTA process, or at least parts of it).	(75,49,52,67)	High confidence	No concerns for all CERQual components.
EUnetHTA			
For health technology policy and decision-making processes, the European Union HTA Network (EUnetHTA) promotes both Information and Consultation models of social engagement with an interest to empower their population are being developed and implemented with an additional aim to empower and include the widest range of their national population as possible.	(90,89)	High confidence	Minor concerns regarding methodological limitations (one theory-based primary (case) study) and minor concerns regarding relevance (partial relevance – social participation model in healthy cities policy decision-making for one primary study).
FRANCE			
The French experience with social engagement with HTA via both State agencies (ANSM - the French national agency for medicines and health products safety - and HAS - the French national authority for health) encompasses information, consultation and participation processes; and has produced a series of recommendations as follows: 1) Patients and users should be able to participate systematically in all health product assessments; 2) Patients' contributions should be an integral part of the assessment dossier throughout the assessment process; 3) To meet the objective of incorporating the patient's viewpoint into the assessment, it must be possible to carry out studies. One of the factors that determines the quality of these studies is patient involvement in their conduct/design; 4) Targeted patient contributions should be requested by assessment bodies without prejudice to the rules of openness and transparency; 5) The transparency requirement with respect to potential conflicts of interest applies to all stakeholders; 6) The training of members of associations in participating and making contributions during	(83)	High Confidence	Minor concerns regarding methodological limitations and serious concerns regarding adequacy of data (data came mainly from one case study description of Round Table held by State Agency committee members).

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
assessment processes is the associations' responsibility.			
GERMANY			
Information, consultation and participation models are used for all the geographical levels and all the policy objectives (HTA, decision-making, and HT development). Social engagement is considered as crucial, as it allows all social actors to bring their perspectives to the HTA process, including, enabling agencies to focus on what is important for citizens/consumers qua patients (an their families, carers, legal representatives) as well as advocates. Eventually, the aim is to promote a steady increase in empowerment, considering that this is facilitated by previous access to: knowledge, health literacy, patient initiative, services, and drugs. In this way, citizens/consumers qua patients (an their families, carers, legal representatives) as well as advocates are more likely to make informed and free choices in health-related contexts, in addition to being more satisfied and compliant with treatments. In this context, adherence is no longer defined as the simple obedience to what is prescribed but as the autonomy that citizens/consumers qua patients (an their families, carers, legal representatives) as well as advocates have to accept the prescribed treatment. Furthermore, HTA organizations should have and open style and innovative culture	(54,49,37,30)	High confidence	No concerns for all CERQual components.
HTAi			
From the Health Technology Assessment international (HTAi) perspective — as the global, non-profit, scientific and professional society for all those who produce, use or encounter HTA — both Consultation and Participation models of social engagement for HTA processes with an interest to empower populations and include the widest range of populations as possible are fostered. The HTAi has recently also proposed a set of ten quality standards for patient involvement in HTA regarding: a) General HTA process: 1. HTA organisations have a strategy that outlines the processes and responsibilities for those working in HTA and serving on HTA committees to effectively involve patients; 2. HTA organisations designate appropriate resources to ensure and support effective patient involvement in HTA; 3. HTA participants (including researchers, staff, HTA reviewers and committee members) receive training about appropriate involvement of patients and consideration of patients' perspectives throughout the HTA process; 4. Patients and patient organisations are given the opportunity to participate in training to empower them so that they can best contribute to HTA; 5. Patient involvement processes in HTA are regularly reflected on and reviewed, taking account of the experiences of all those involved, with the intent to continuously improve them; and b) For Individual HTAs: 6. Proactive communication strategies are used to effectively reach, inform and enable a wide range of patients to participate fully in each HTA; 7. Clear timelines are established for each HTA, with advance notice of deadlines to ensure that appropriate input from a wide range of patients can be obtained; 8. For each HTA, HTA organisations identify a staff member whose role is to support patients to contribute effectively to HTA; 9. In each HTA, patients' perspectives and experiences are documented and the influence of patient contributions on conclusions and decisions is reported; 10. Feedback	(12,19,51,62)	High confidence	No concerns for all CERQual components.

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
is given to patient organisations who have contributed to an HTA, to share what contributions were most helpful and provide suggestions to assist their future involvement.			
INDIA			
Information, consultation, and participation processes are used, at the national level, for HTA. The Community-Based Participatory Research (CBPR) approach was used. The aim is to mobilize the community, trying to understand their needs by means of carefully designed and flexible tools. Facilitators were: the accurate selection of participants, community involvement in research design, the use of flexible tools, and others. In this way, even hard-to-reach individuals can be engaged. Marginalized and disadvantaged groups are especially targeted by the CBPR approach, as it aims precisely at promoting equitable engagement of the community to eliminate disparities in population health by addressing power imbalances. Communities that lack resources and skills often feel less motivated to engage in initiatives, so the CBPR aims at tacking this problem. By drawing on communitarian or tribal structures, it is possible to guarantee the post-intervention sustainability of initiatives	(39)	Moderate confidence	Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
IRAN			
Information, consultation, and participation processes are used, at the local and national level, in the context of HTA. The goal was to understand the community's needs by means of flexible tools, as well as to measure the community's level of empowerment. Facilitators were: the accurate selection of participants, community involvement in research design, the use of flexible tools, and others. Marginalized and disadvantaged groups are especially targeted, by means of the CBPR, which aims precisely at promoting equitable engagement of the community to eliminate disparities in population health by addressing power imbalances. By drawing on communitarian or tribal structures, it is possible to guarantee the post-intervention sustainability of initiatives.	(39,59)	High confidence	No concerns for all CERQual components.
IRELAND			
Consultation is practised, at the national level, in the context of HTA. Participants could volunteer for a citizen consultation guided by a facilitator. They were invited to express their feelings and hopes towards the future of Europe. Difficulties included: the formulation of a final view which would not reflect the facilitator's preference; the expression of every participant's views; and the failure to include every type of opinions. Facilitators included: the carefully designed selection procedures; and the writing of individual statements by participants. Eventually, the event was successful and managed to collect unbiased opinions.	(85)	Moderate confidence	Serious concerns regarding adequacy of data (data comes mainly from one primary (case) study).
ISRAEL			
Information, consultation, and participation processes were used, at the national level, for HTA and policy-making. This is line with the notion that governments have to always consult citizens before taking crucial decisions. Engagement helped participants realize the difficulties entailed by decision-making.	(34,86)	High confidence	No concerns for all CERQual components.
ITALY			

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
Information, consultation, and participation processes are used, at the national level, for health-technology policy-making, and health-technology development. Whenever research was conducted, the goal was to influence researchers' views through the inputs provided by the public. Engagement schemes have to account for local variations.	(40,30)	High confidence	No concerns for all CERQual components.
KENYA			
Information and participation processes are used, at the local level, in the context of HTA implementation and monitoring.	(88)	High confidence	Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
NETHERLANDS			
From the Netherlands experience, or health technology assessment, development, implementation and monitoring processes, the Netherlands promotes all three models of social participation (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented with an additional aim to include the widest range of their national population as possible, at both local and national levels. If we consider both development and implementation of social engagement methods as processes — i.e. soft/social technology — the Netherlands is at the forefront – alongside Canada – as vanguard countries that are developing truly innovating strategies to promote and support social participation sponsored by health professionals, health technology assessment and policy/decision-makers and organisations, as well as industry, research institutes and members from society. Sponsors provide funding, coaching and other support for Dutch healthcare organisations that engage citizens/consumers qua patients (families, carers, legal representatives) as well as advocates in designing, delivering and evaluating healthcare technologies, as well as more focused, purposeful participatory processes informed by evidence from their own or others' experiences by nurturing a climate conductive for social engagement (mobilizing the community, fostering respect and trust, developing an attitude shift for professionals and utilising a partnership — i.e. a citizen science-approach) and empowerment. Empowerment, within this context, can be regarded as both a process and an outcome. It may also be seen as an enabling process whereby health care professionals collaborate with patients to help them acquire knowledge and resources and whose outcome is a patient with greater ability to exercise control, manage his/her condition and to make informed decisions, as well as collaborate with the design of (new) technologies.	(84,49,30,36,41)	High confidence	No concerns for all CERQual components.
NEW ZEALAND			
Information, consultation, and participation processes are used, at the local and national levels, for health technology implementation, monitoring, assessment, and policy-making. However, it is important to conduct well-studied processes in order not to overburden people with, for example, an overload of information or the conduct of too technical discussions.	(75,49,40)	High confidence	No concerns for all CERQual components.
NORWAY			
For health technology development, implementation and monitoring processes, the	(75,30)	High confidence	Minor concerns regarding adequacy of

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
Norwegian experience promotes all three models of social participation (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented with an additional aim to include the widest range of their national population as possible.			data (data came mainly from two primary (case) studies).
PERU/UGANDA			
Participation processes are used at the local level, in the context of health tehcnology implementation and monitoring. Health Facility Committees are established in the units providing health care. The goal is to enhance accountability in relation to the public, promoting co-management of resources. Outreaching activities aim at promoting health and fostering health-seeking behaviours. The views of the public must be transmitted to health facilities. Barriers to engagement were the hierarchies (social, economic, cultural, geographic, and political) that existed previous to the formation of committees.	(88)	High confidence	Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
SPAIN			
For health technology assessment, the Spanish experience promotes the Participation model of social engagement with an additional aim to include the widest range of their national population as possible, at the local level.	(76)	Moderate confidence	Serious concerns regarding adequacy of data (data came mainly from one primary (case) study).
SWEDEN			
Information, consultation, and participation approaches were used, at the national level, for health technology implementation and monitoring. For so doing, it is important to take into consideration the role played by different stakeholders, including the public (which might be lacking relevant information) and owners of technology (whose interests might distort the engagement process). A barrier identified by the Swedish experience is underrepresentation, for example, of younger generations.	(75,94)	Moderate confidence	Moderate concerns regarding relevance (partial relevance for one case study) and adequacy of data (data came mainly from two primary (case) studies).
TAIWAN			
Participation processes are used, at the national level, for health technology policy and decision-making. A two-day civic groups forum was organised. Initially, participants were provided with divergent opinions given by experts. This was followed by group discussion. Conclusions can be reached by either deliberative methods or polling methods. Barriers included a sense a mistrust and division among participants. Facilitators included success in disseminating a sense of communitarian participation in the group, and the notion that participation has a concrete impact in health policies.	(31)	Moderate confidence	Serious concerns regarding adequacy of data (data came mainly from one primary (case) study).
UK			
For all stages of the health technology cycle, including its development, assessment, policy/decision-making, implementation and monitoring processes, all three models of social engagement (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented around the UK with an additional aim to include the widest range of their population as possible, especially at the national level. If we consider both development and implementation of social engagement methods as processes — i.e. soft/social technology — the UK is where more financial, institutional and governmental investments have been made to promote and support social participation strategies sponsored by health professionals and technology	(75,49,34,91,105,44,40,94,59, 98,95,93,92,60,46,96,9,39,67, 30,56)	High confidence	No concerns for all CERQual components.

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
assessment and policy/decision-makers and organisations. Sponsors provide funding, coaching and other support for UK healthcare organisations that engage citizens/consumers qua patients (families, carers, legal representatives) and advocates in designing, delivering and evaluating healthcare technologies, as well as more focused, purposeful participatory processes informed by evidence from their own or others' experiences by nurturing a climate conductive for social engagement (mobilizing the community, fostering respect and trust, developing an attitude shift for professionals and utilising a partnership — i.e. a citizen science-approach) and empowerment.			
Empowerment can be regarded as both a process and an outcome. It may also be seen as an enabling process whereby health care professionals collaborate with patients to help them acquire knowledge and resources and whose outcome is a patient with greater ability to exercise control, manage his/her condition and to make informed decisions. Empowerment has a few dimensions that can become part of training and capacity-building activities — amenable of qualitative/quantitative measurement—such as: participation in decision-making, gaining control, knowledge acquisition, coping skills, positive attitude, sense of meaning to patients' experience with disease, motivation, trust, self-care, sharing and capacity-building. The UK experience has developed a conceptual map to evaluate the level of empowerment of citizens/consumers qua patients (families/carers/legal representatives) and advocates as, according to the stakeholder group's ethos: a) patients have rights, responsibilities and opportunities relating to: a.1) autonomy; a.2) self-determination; a.3) power within the healthcare relationship; a.4) optimising healthcare service; b) healthcare providers/professionals have responsibilities to: b.1) respect patient's autonomy; b.2) adopt a partnership style within the healthcare relationship — in order to develop and implement individual-focused empowering interventions (e.g. patient-centred intervention; shared decision-making; motivational interviewing; counselling; health coaching), and to moderate personal characteristics, training, personal values and professional goals; and c) healthcare systems have responsibilities to: c.1) optimise healthcare-service use c.2) maximise patient health status and well-being — in order to develop and implement group-focused empowering interventions (e.g. expert patient programme, chronic disease self-management programme, personalised care planning and patient education). All such levels of empowerment are moderated by: political context, health priorities, legislation, and culture. The conceptual map also identified indicators of citizens'/consumers' qua patients' (families/carers/legal representatives) and advocates' empowerment level, according to their: a) self-efficacy; b) knowledge, skills, attitudes and self-awareness necessary to influence their own health behaviour; c) perceived personal control over health & healthcare; d) sense of meaning and coherence about their condition; e) health literacy; f) feeling respected; g) behaviours — things patients "do" (participation in shared decision-making — taking active roles in healthcare consultations and/or making informed decisions about their health and/or care — and/or managing their own health and/or care (self-management) — choosing personally	(49,91,105,40,59,98,95,93,92, 60,46,9,39,67, 30,56)	High confidence	No concerns for all CERQual for all CERQual components.

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
meaningful, realistic health-related goals, and/or taking steps to achieve those goals — and/or empowering themselves — participation in patient support/advocacy groups, and/or using the internet to collect/share health information & support). All such indicators are moderated by: context, personal characteristics, illness-related circumstances, social support, and personal values. There are also individual outcomes, such as: a) adaptation to chronic illness; b) quality of life; c) well-being/ satisfaction with life; d) independence; as well as clinical outcomes (such as health status) that are key to evaluate indicators of their level of empowerment.			
HTA organisations, especially the National Institute for Health and Care Excellence (NICE) and the Scottish Medicine Consortium (SMC) have been developing and implementing social engagement initiatives that balance the more encompassing approach proposed by the Participation Model as well as Consultation strategies. Aiming to devise meaningful approaches to actively engage society in informed and increasingly politically charged debates about publicly funded goods such as health technologies and social services, the main recommendation from UK sponsors is to develop a combination of both Consultation and (direct) social Participation strategies to synergistically increase the citizens and consumers qua patients' influence on health professionals, technology assessment and policy/decision-makers and organisations, and, ultimately, health systems. In this sense, the UK experience is to improve citizens/consumers qua patients' (and families/carers/legal representatives') and advocates skills and knowledge, giving them a sense of responsibility for the decisions and increasing their participation in specific contexts according to the stage in the health technology development and/or assessment process. Participation strategies are usually more relevant at both beginning and end of health technology assessment's process; whereas Consultation methods have been more pertinent throughout the evaluation process. Nevertheless, various forms of engagement could be combined, such as limiting the collaboration of patients (and families/carers/legal representatives) with direct links to the health technology in question to certain stages of the process, while involving citizens'/consumers' qua patients' representatives as partners in the health technology development and/or assessment committee on a full-time basis. Ultimately, it is important to engage society as early as possible — not once a recommendation has been made — and evaluate social engagement practices to provide evidence to inform future initiatives for introducing the society's perspective in such processes and convincing managers of its relevance and utility. It is importante however to outline that unfortunately, when lay persons (or expert patients) sit on prestigious medical committees their contribution may be unconsciously undermined, because "they do not have access to dominant forms of capital that professionals have access to", and their participation is deemed as tokenistic.	(75,49,34,91,105,44,40,94,59, 98,95,93,92,60,46,96,9,39,67, 30,56,97)	High confidence	No concerns for all CERQual components.
NICE is a leading HTA Organisation both sponsoring and innovating in social engagement models and methods for universal health coverage health systems such as the UK's NHS. Its social engagement approaches encompasses all three models of Information, Consultation and Participation. Participation occurs at NICE through various routes,	(49,34,91,95,92,67, 30)	High confidence	No concerns for all CERQual components.

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namely: a) Technology Appraisal Committees — operate as a standing Advisory Committee of the Board of the Institute; receive, consider, and interpret evidence on the clinical and cost effectiveness of health technologies referred to it; develop guidance for the NHS, in accordance with the published methods and processes of health technology appraisal; submit its recommendations to the Institute's Guidance Executive, which will act under delegated powers of the Board in considering and approving the guidance for publication — membership: number of members: 125 (30–33 members across four committees); number of patients: 12 lay members, one of whom can be identified as being linked to a patient organization; tenure of members: 3 years, with the possibility to extend to 10 years—way of working: scheduled meetings to assess specific technologies; b) Additional Standing Committees — additionally to the four Technology Appraisals Committees, NICE also has a number of other standing advisory committees, all of which have lay membership — Interventional Procedures Advisory Committee; Medical Technologies Advisory Committee; Diagnostics Advisory Committee; Public Health Interventions Advisory Committee; Research and Development Advisory Committee; Quality and Outcomes Framework Indicator Committee; NHS Evidence Accreditation Advisory Committee — membership: number of members: 25–30 members on each committee; number of patients: two lay members on each standing committee; tenure of members: 3 years, with the possibility to extend to 10 years — way of working: each committee has its own specific remit, and meets at scheduled intervals; c) Partners Council – has a statutory duty to meet annually to review the NICE annual report; provides a forum for the exchange of ideas, concepts, and future plans – membership: number of members: 49 places, 37 filled; number of patients: 6 places that could be classified as public or patient representatives, 4 identified as being linked to a patient organization; tenure of members: 3 years, with the possibility to extend to 10 years — way of working: meet twice a year; d) Citizens Council — responsible for ensuring the views of the public underpin the thoughts and processes of NICE; councillors evaluate the social and moral issues raised by NICE guidelines — membership: number of members: 30; number of patients: members of the public who may or may not be patients at the time they meet and deliberate issues; tenure of members: 3 years; every year 10 members are replaced — way of working: meet twice a year for 3 days at a time to deliberate key issue (e.g. health inequalities); report produced for NICE Board consideration and incorporated into Social Value Judgments guidance, which is provided to Appraisal Committees; e) Guideline Development Groups (GDGs) — independent GDG for each clinical guideline being developed; group members include health professionals and patient/carer members with relevant expertise and experience; applications are open and registered stakeholder organizations are encouraged to submit applications; looks at the evidence available and considers comments made on draft versions of the guideline issued for consultation before making final recommendations; use what has been termed as Colloquial Evidence — membership: number of members: 35 groups at any one time, with an average of 15 members on each group; number of patients: at			

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least two patient or carer members on each group; tenure of members: specific to guideline (generally 9–18 months) — way of working: specific to guideline (usually a meeting once every 4–6 weeks); f) Public Health Program Development Groups (PDGs) — one independent PDG for each public health program topic being developed; looks at the evidence available and considers comments made on draft versions of the guidance issued for consultation before making final recommendations — membership: number of members: 14 groups at any one time, with an average of 20 members on each group; number of patients: at least 3 lay ('community') members on each group; tenure of members: 18 months — way of working: every 6 weeks; g) Steering Groups/Other Expert Groups — a variety of groups of experts attached to different programs within NICE — groups such as the Commissioning Programme Steering Group, the Patient Access Scheme Liaison Unit Expert Panel, and the various Topic Expert Groups convened to develop Quality Standards — membership: number of members: varies; number of patients: at least two lay members on each group; tenure of members: specific to activity that the group is set up to steer — way of working: specific to activity that the group is set up to steer.			
USA			
For health technology assessment and policy/decision-making processes, all three models of social engagement (Information, Consultation and Participation) with an interest to empower their population are being developed and implemented around the US with an additional aim to include the widest range of their population as possible, especially at the national level. If we consider both development and implementation of social engagement methods as processes — i.e. soft/social technology — the US is promoting sponsors to provide funding, coaching and other support for US healthcare organisations that engage citizens/consumers qua patients (families, carers, legal representatives) and advocates in designing, delivering and evaluating healthcare technologies, as well as more focused, purposeful participatory processes informed by evidence from their own or others' experiences by nurturing a climate conductive for social engagement (mobilizing the community, fostering respect and trust, developing an attitude shift for professionals and utilising a partnership — i.e. a citizen science-approach) and empowerment.	(49,45,40,78,80,82, 59,81, 77,39,56)	High confidence	No concerns for all CERQual components.
Empowerment can be regarded as both a process and an outcome. It may also be seen as an enabling process whereby health care professionals and decision-makers collaborate with citizens/consumers qua patients (families, carers, legal representatives) and advocates to help them acquire knowledge and resources and whose outcome is an end-user with greater ability to exercise control, manage his/her condition and to make informed decisions. Empowerment has a few dimensions that can become part of training and capacity-building activities — amenable of qualitative/quantitative measurement—such as: participation in decision-making, gaining control, knowledge acquisition, coping skills, positive attitude, sense of meaning to patients' experience with disease, motivation, trust, self-care, sharing and capacity-building. The US experience has	(49,40,78,80,59,81, 39,56)	High confidence	No concerns for all CERQual components.

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outlined four dimensions of activation (empowerment) and engagement, namely that citizens/consumers qua patients (families, carers, legal representatives) and advocates should: a) participate in policies and practices to prevent disease through health promotion and addressing underlying behavioural and social determinants of health; b) engage in direct care provision; c) participate in organisational quality improvement and governance; and d) participate in determining 'end-of-life' preferences for care. Both measurement and evaluation of empowerment are not simple tasks, as they are designed to increase different stakeholders' capacity to conduct their own evaluations and to increase the control of actions taken to improve health technologies' impact. Therefore, it is expected that not only do the agency staff implementing the health technology and/or social engagement intervention gain control over the health/social technology but also that the recipients and consumers of such health/social technology have an important voice in decisions that affect such technology's implementation, being seen as experts with respect to community issues and the services they provide.			
WHO			
Regarding health technology development processes, social engagement methods with potential end-users and other stakeholders, including citizens/consumer qua patients (families, carers, legal representatives) and advocates, using well-constructed questions, and possibly using Delphi-like procedures have been promoted at all levels. There is not an aim to empower such groups; however, the assumption is to include the widest range of populations as possible. Barriers to the implementation of Delphi-questionnaires for priority-setting identified by the WHO experience are: a) the use of summary burden of disease measures, such as disability adjusted life years (DALYs), have been criticised for focusing on disease rather than resource use and interventions, because of the assumptions about values inherent in such measures, and because of the technical limitations of such measures; b) important methodological issues need to be addressed to ensure that the procedure used is valid, reliable, consistent and useful for policy making; c) debates and limited data regarding social engagement in priority setting (from a small survey in Australia that the public overwhelmingly want their preferences to inform priority-setting decisions); d) avoid expecting nationally developed guidelines to cover every operational issue for every kind of setting, as guidelines that leave too much to be decided at the local level or during implementation run the risk of being ignored, misused, and modified in ways detrimental to patients — this is even more so for internationally developed guidelines. Facilitators to the implementation of Delphi-questionnaires for priority-setting identified by the WHO experience are: a) priority setting at each level should draw on the strengths and minimize the limitations of international, national and local organizations, so both centralised and decentralised processes that take account of these different strengths and limitations, as well as needs; b) the application of criteria for priority setting requires judgements, therefore, it is important to explicit criteria, to ensure that these judgements are made openly, and that they reflect the priorities of WHO's member states, particularly those of low and middle-	(106) *Updated (14 Nov 2019)	High confidence	Minor concerns regarding adequacy of data (data comes from one (non-systematic) review of systematic reviews)

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income countries; c) criteria for establishing priorities should be applied using a systematic and transparent process, which also considered unmeasured factors because data to inform judgements are often lacking; d) groups that include stakeholders and people with relevant types of expertise should make decisions, and ensure full participation by all members of the group; e) all processes should be documented and open to inspection.			
ZIMBABWE			
Consultation and participation processes are used, at the local level, for health technology implementation and monitoring. The objective is to understand how health facilities operate, as well as to build up connections between those facilities and the communities served by them.	(88)	Moderate confidence	Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).

Tabela 4 – Tabela de Achados de Experiências sobre Modelos de Participação Social em Processos de ATS e Etapas Anteriores (Formulação de Políticas, Desenvolvimento) e Posteriores (Implementação e Monitoramento) de (Novas) Tecnologias em Saúde

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INFORMATION MODEL			
The community-based participatory research (CBPR) approach helped guarantee the dissemination of findings, and knowledge exchange between community and academic partners. The CBPR approach also guarantees knowledge exchange. The information disseminated to the community must be meaningful, thus enhancing the relevance of health promotion messages. The CBPR approach aim is to facilitate knowledge sharing. The dissemination of research findings is another key goal of the CBPR approach. All the information provided must be meaningful from the community's perspective, so cultural and access barriers can be overcome, further enhancing the relevance of health messages.	(39)	High confidence	Context: Africa, Bangladesh, China, India and Iran Explanation: Minor concerns regarding adequacy of data (data comes mainly from one systematic review and there is no specific data extracted that could build this finding for each country in Africa as well as for Bangladesh, China, India and Iran).
As means to educate and consequently empower society at large — as part of an enabling process whereby sponsors (healthcare professionals and policy/decision-makers) collaborate with citizens and consumers qua patients to help them acquire knowledge and resources, and whose outcome is a mature citizen with greater ability to exercise e control, manage his/her condition and to make reasoned judgements on complex issues for informed decisions, coping skills, positive attitude; sense of meaning to one's experience with disease, motivation, trust, self-care, sharing and capacity-building – there are a few barriers and facilitators to this model. It is important to avoid the use of technical language and acronyms, and to prioritise the deployment of balanced relevant information that adds context to health technology development, assessment and policy/decision-making data, and includes quality of life and clinical outcome measures. It is also important to ensure that lay people understand their role and issues addressed, due to society's unfamiliarity with the health technology assessment, policy/ decision-making and development processes. Citizens (as ordinary people who are unfamiliar with the issues), consumers (who provide relevant personal experience e.g. of illness) and advocates (who possess technical expertise or partisan interests) need mentoring, training, support, an induction day, well-defined outcome-focused presentation, open working style and innovative culture in health technology development, assessment and policy/decision-making organisations. In this sense, health technology development, assessment and policy/decision-making organisations are also generally unfamiliar with consumer and/or advocates organizations' modus operandi therefore, as educational and skills forging processes may be time- and resources-consuming, the third recommendation is to design adequate (tailored) educational and/or empowering/advocacy capacity building programs that considers legal and regulatory constraints associated with communication with citizens and consumers qua patients in	(49,107,104,40,15,61,59,60) *Updated (14 Nov 2019)	High Confidence	Context: Australia Explanation: Minor concerns regarding methodological limitations (lack of reviewers' reflexivity as we cannot tell if researchers collecting data were also the health professionals delivering care, which could contribute to biased data collection).

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many jurisdictions. Sponsors of social engagement strategies within the Information Model must also consider new media options (i.e. social media) and methods to reach society, notifying social actors about new products in a timely-manner to promote health literacy of active citizens and consumers qua patients. Such organisations must also formally audit the process to grant transparency and help solve uncertainty, fairness, equity, affordability and impact issues regarding the social engagement model. Formal social participation at audit process constitutes an innovative citizen science-based alternative for the development of soft/social technology that is an already validated decision-making processes by all social actors involved in health technology development, assessment and policy/decision-making.			
Citizens' juries organized had the presence of specialists who provided participants with relevant information (expert testimony). In some juries, written information was also provided, in the form of workbooks, for example.	40	High confidence	Context: Brazil Explanation: No concerns for all CERQual components.
Although it is a relatively passive type of social participation, real, relevant, and realistic public engagement cannot take place without more sophisticated social information mechanisms. The Canadian experience illuminates on a series of recommendations on barriers and facilitators regarding improved methods for establishing linkages and for information flow from health technology assessment, development and policy/decision-making sponsors to society, in its various groups, especially focusing on social (electronic) media and other innovative methods using existing community networks. • **Establishing the framing of the social engagement model and making this information clearly available in a stepwise manner to ensure access, legitimacy and accountability of participation activities is key. Framing comprises process issues (such as defining partners, developing a common vision, clarifying roles and responsibilities, defining a decision-making process and assessing participatory activities) and knowledge requirements (standardised information, education and training). Sponsors must select and highlight background standardised materials on aspects that will be presented throughout consultation and/or participation methods and the ways in which problems, arguments, information and positions will be presented in advance of each meeting — including health technologies assessment and development evidence summaries and draft recommendations, relevant review articles, newspaper clippings and a workbook summarising key attributes of each technology and the discussion questions. Participants can also be asked to prepare questions prior to participatory activities. Preparation is important in supporting social representation role and expertise as it has contributed to the engagement intervention's impact by building the participants' sense of credibility and their ability to contribute specific expertise to the engagement method task. In this sense, it is important to present clarification questions in a nonthreatening environment and to build confidence so citizens/consumers qua patients (and families/carers/legal representatives) are placed in a favourable position to meet with health professionals and decision-makers – i.e. they become patient advocates. For such purposes, it is important to build participants' sense of legitimacy as public representatives (critical to influence group decisions) and of a collective 'social representative' identity so that participants' progress**	(53,49,65,40,38,73,66,29,42,60, 39,55,67,56,28,101,69,70,71,72)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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in understanding their representation role, and also how their legitimacy and credibility evolved over time, is partly framed by how they are recruited and selected, their opportunity to interact with other members of society, and their preparation. In this sense, social engagement approaches under the Information model must not only provide citizens/consumers qua patients (and families/carers/legal representatives) participants with enough information to understand the technical language used by professionals but also support their ability to become a credible source of knowledge for professionals. Consequently, as they become more solidly grounded in their roles, both social representatives and professionals also become more aware of the limits of their own expertise and actively engage in a process of mutual learning and influence, as desired as a social appropriation of scientific knowledge (i.e. empowerment) strategy. For such purposes, it is also important to provide information, education and training support for citizens/consumers qua patients (and families/carers/legal representatives) in lay language, avoiding technical terminology and acronyms. The National Institute for Health and Care Excellence (NICE), pharmaceutical industries (such as eMEET — Medicine Evaluation Educational Training — by Eli Lilly) and other independent groups from university departments (such as the *Université de Montréal* and governmental agencies (such as the European Patients' Academy) offer in person and online educational training for patient advocates. • **Educating and building capacity amongst health professionals and health technology assessment and development implementers in order to clarity misconceptions about what each social engagement strategies really mean is essential. In this sense, it is important to have clarity about the framing of citizens'/consumers' qua patients' (and families/carers/legal representatives) and health professionals' and/or social engagement implementers' roles in the participatory process. In this sense, capacity building of professionals and implementers must encompass issues of leadership and commitment at all levels of the sponsor organisation outlining the centrality in following through with participants long after the consultation participation activity is finished and in the clarity of feedback information about the participatory process.** • **Providing access to support and updated standardised information resources in an ongoing manner, via workshops and/or online guidelines, as well as feedback that clearly highlights the original contributions made by citizens/consumers qua patients (and families/carers/legal representatives) on the final decision regarding health technology assessment and policy/decision-making processes based on their values and experiential knowledge is important. For such purposes, it is important to document meeting outcomes including the value of social actors' input and formally audit the process as, sometimes, providing citizens/consumers qua patients (and families/carers/legal representatives) with sufficient health information may (not) reduce their anxiety. The idea is to guarantee bidirectional translation and implementation of information onto social engagement activities so that participants are adequately and sufficiently motivated;** • **Another key strategy to achieve optimal social engagement is to disentangle the role of**			

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patient advocacy groups in patient engagement, as emotional appeals are perceived as lacking credibility and relevance, pointing to a common misunderstanding of the kinds of information should be included in the patient submission process - i.e. the right information from patients' groups in the right format. Therefore, there should be better support of the patient submission process, on the part of HTA agencies by insuring clarity of communication about the purpose of the patient submissions or broader social participation process and about what is expected from each group - as in all HTA sponsors must have a clear vision for social engagement at the organisational level. In this sense, it would be important to suggest a role for advocacy group members as information sources for HTA that can be disconnected from their interests in shaping the outcome of related policy and decision-making processes – i.e. in providing real-world evidence (based on data collected from sources outside of clinical trials such as observational or registry studies, retrospective database collection and case reports and reports of patient experience) as well as colloquial evidence, such as Patient-Reported Outcomes (PROs); • **Regarding language, a shift from considering what is "clinically relevant" to what is "patient important" or of "personal significance" could result in a very different set of recommendations being made by HTA reports and clinical guidelines.**			
Citizens are provided with information pertaining to technological devices and processes. Such information must be based on the best available and clearest data. In this way, the various agencies and actors providing information should not play contradictory roles.	(75)	Moderate confidence	Context: Chile Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one primary (case) study).
Citizens were provided with information pertaining to devices and processes. Citizens must receive information that is clear and in line with the best evidence available.	(75,49,52,67)	High confidence	Context: Denmark Explanation: No concerns for all CERQual components.
EUnetHTA outlines the importance of deploying different methods to present data (textually or graphically) to stakeholders as this may affect their perceptions around the issue being discussed. It is also important to be aware of language when producing information materials for groups of people who do not speak the same language, as feedback responses suggest that while some respondents are fluent in English, others struggled to understand the subtleties of the questions and communicate detailed responses, thereby generating data of variable quality.	(90,89)	High confidence	Context: EUnetHTA Explanation: Minor concerns regarding methodological limitations (one theory-based primary study) and minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies)
Provision of information is realized in the context of Analytic Hierarchy Process, whereby explanation of endpoints is given in a jargon-free language. Another strategy mobilized is the promotion of information sharing between different stakeholders (patients, physicians, external advocates, and others). It is important that information be provided in such a way that it can be trusted by those receiving it.	(54,37,30)	High confidence	Context: Germany Explanation: No concerns for all CERQual components.
The conduction of mini-publics and health parliaments was informed by the provision of some relevant information. In the case of health parliaments, participants were provided with written materials (including library materials), as well as a description of the dilemmas	(34,86)	High confidence	Context: Israel Explanation: No concerns for all CERQual components.

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surrounding the issues at stake. In addition, health policy consultants were available for helping participants solve doubts. Provision of information can be impaired, however, whenever the necessary evidence is lacking.			
Initiatives such as community mappings were mobilised. The objective was to promote clarity and transparency in contexts of health care.	(88)	High confidence	Context: Kenya Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
Regarding empowerment strategies, the Dutch experience outlines some key findings with two recruitment approaches: • **the Participation Chain Model: proposes a "systematic framework for understanding what makes public service users participate", covering the full range of conditions necessary for participation, including:** **a) individual and collective benefits that might derive from participation, and which thus motivate people to participate (demand-side factors);** **b) participants' prior resources, and the mobilisation process that encourages them to participate (supply-side factors);** **c) institutional dynamics of participation (i.e. the way the participation process itself, as governed in part by wider institutionalised expectations and priorities, encourages or discourages participation). It further outlines the importance of creating 'hybrid spaces' that foster the articulation of alternative knowledge/voices, providing a forum for more equitable exchange, and further creating 'receptive social environments' in which the powerful are willing to listen (unlike 'invited spaces' of governance). In this sense, a key step towards empowerment is direct mobilization (incentivising 'vote of confidence' and a sense of entitlement for minorities to practise their citizenship and exploit opportunities for participation).** **The Dutch experience has outlined a few facilitators to the implementation of the participation chain model as an empowerment method, such as:** **a) ensuring involvement of marginalised groups to emphasise that each individual link in the participation chain (model) needs to be made as strong as possible;** **b) strengthening the ability to assess the relative importance of their factors but cannot reveal such interdependencies, which require qualitative, interpretive analysis;** **c) importance of reaching user organisations beyond the 'participation-ready' volunteers (user organisations are becoming less committed to mobilising voiceless groups and equipping them for participation, as many are overloaded with requests to participate in advisory meetings with government, reducing their capacity to reach out to grassroots users; therefore, many have also chosen to professionalise to increase their capacity to influence policy, their mobilisation efforts becoming a 'search for the right volunteers' who already have the competences required – recruiting only the most competent users has implications for representativeness and inclusiveness, especially among marginalised groups) and work actively on the incentives and resources needed by marginal groups, and**	(84,41,30)	High confidence	Context: Netherlands Explanation: Minor concerns regarding adequacy of data (data comes mainly from three primary (case) studies)

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the institutional dynamics to sustain their engagement in the 'hybrid spaces'. • **the Neocorporatist Model emphasises the engagement of organised civil society groups, as patients in the Netherlands have organized themselves at different levels: there are hundreds of disease-specific patient organizations; individual patients can become members of these organizations; disease-specific patient organizations are members of larger umbrella organizations that work together in even larger regional and national umbrella organizations; there are also non-disease specific organizations catering to certain groups in society (elderly and psychiatric patients); most work is carried out by volunteers; 70% of patient organizations are associations have an internal democratic structure in place, their members can give input and decide on the course of the organizations, mostly through general meetings. Patient organisations are recognised by the State and are called the third party in health care next to providers and insurers, so increasingly asked to participate in decision-making processes, and are heavily subsidised, enabling them to play this active role. Therefore, patient organisations participation possibilities are:** **a) consultation by the Ministry of Health Welfare and Sport, Parliament, Government Supervisory and Advisory Bodies and Municipalities;** **b) influence healthcare providers via:** **b.1) contribute to patient perspective in guideline development groups and participate in the development of indicators used by the Dutch healthcare inspectorate;** **b.2) develop their own quality criteria and attribute quality marks to providers who then provide care according to these criteria;** **c) engagement with healthcare improvement projects and with the training of professionals;** **d) smaller organisations can sometimes focus more on representing the interest of individual members and intervene when they feel that one of their members is not receiving the appropriate care;** **e) patient organizations are also active in decision making on health research in different ways, playing an intermediary role between researchers and patients that are needed as research subjects, as they are increasingly consulted in the development of research agendas and in research proposal assessment and supervisory committees (i.e. as in citizen science initiatives).** **Facilitators identified are the same as for the Participation Chain Model (above).**			
People were informed in the framework of (online) ranking and choosing techniques. Information can be provided in numeric, textual, or graphic form. Finally, in the context of citizens' juries, experts provided participants with oral evidence. Ideally, information should be neutral (not market-informed), present (not dealing with future cases), and official (not shaped by personal convictions). However, the provision of too large amounts of information can be overwhelming. In this way, a controlled provision of information (through sorted lists, for example) should be sought.	(75,49,40)	High confidence	Context: New Zealand Explanation: No concerns for all CERQual components.
e-Health methods were used as channels to enable provision of information in different formats (numeric, textual, and graphics). However, care should be taken to avoid an	(75,94)	High confidence	Context: Sweden Explanation: Moderate concerns

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information overload.			regarding adequacy of data (data comes mainly from two primary (case) studies).
Although information is a relatively passive type of social participation, real, relevant, and realistic public engagement cannot take place without more sophisticated social information mechanisms. The UK experience illuminates on a series of recommendations on barriers and facilitators regarding improved methods for establishing linkages and for information flow from health technology assessment, development and policy/decision-making sponsors to society, in its various groups, especially focusing on social (electronic) media and other innovative methods using existing community networks. In the sense of electronic health (e-Health) — which encompasses technology both as a tool to enable a process/function/service and as the embodiment of e-Health itself (e.g., a health website on the Internet), as a means to expand, assist, or enhance human activities, rather than as a substitute for them — web-based support to citizen'/consumers' qua patients' (and families/carers/legal representatives) and advocates' choices comprises 'isolation' (provision of technological devices that describe the framework for choice of, for example, a primary health care provider or a school, and the search for available units) and 'examination' (provision of technological devices that investigate and compare available choices based on, for example, waiting times and quality indicators) of information. Regarding facilitators, there are differences to be used by designers interested in understanding how calculated choice may be supported for: a) 'isolation' — as far as the availability of information about rights and in the search devices for alternatives; and b) 'examination' — as far as the kind and availability of information and the types of devices for making comparisons. • **Provision of information about the right of choice is important, as well as well-defined outcome-presentations, lay language background texts (including factsheets about changes to specific services, answers to frequently asked questions, colloquial evidence, updated prevalence data), making patient-carer perspectives explicit, changing the focus of vignettes, and the awareness of the full repertoire of potential types of information (extensive amounts of information can be provided about available options and opportunities via Web-based decision support — for example, in numeric, textual, or graphic form ["format"], using neutral information (vs. marketing information), information about present circumstances (vs. future opportunities), and user evaluations from official investigations (vs. more personal evaluations of opportunities ["aim"]). Another facilitator (also of empowerment) is provision of citizens'/consumers' qua patients' (families/carers/legal representatives') and advocates' mentoring, training, support, and the presence of an induction day prior to each type of social engagement model and method.** • **Educate and build capacity amongst health professionals and health technology assessment and development implementers in order to clarity misconceptions about what each social engagement strategies really mean. In this sense, it is important to have clarity about the framing of citizens'/consumers' qua patients' (and families/carers/legal**	(75,49,105,44,40,94, 98,93,92,60,46,96,9, 39,67,30, 56)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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representatives) and health professionals' and/or social engagement implementers' roles in the participatory process. In this sense, capacity building of professionals and implementers must encompass issues of leadership and commitment at all levels of the sponsor organisation outlining the centrality in following through with participants long after the consultation participation activity is finished and in the clarity of feedback information about the participatory process. • **Provide access to support and updated standardised information resources in an ongoing manner, via workshops and/or online guidelines, as well as feedback that clearly highlights the original contributions made by citizens/consumers qua patients (and families/carers/legal representatives) on the final decision regarding health technology assessment and policy/decision-making processes based on their values and experiential knowledge. For such purposes, it is important to document meeting outcomes including the value of social actors' input and formally audit the process as, sometimes, providing citizens/consumers qua patients (and families/carers/legal representatives) with sufficient health information may (not) reduce their anxiety. The idea is to guarantee bidirectional translation and implementation of information onto social engagement activities so that participants are adequately and sufficiently motivated.**			
Although information is a relatively passive type of social participation, relevant, and realistic public engagement cannot take place without more sophisticated social information mechanisms. Therefore, although 'high-touch' approaches — dedicated note-taker summarising contributions from stakeholder and circulates minutes; presenting results of research back in town hall meeting or through paper newsletters; engaging minorities and individuals from groups who are underrepresented in 'high-touch' engagement activities to assist with translating results — reduce exclusion of low literate and others who might find technology (computers, smart phones, etc.) challenging, the US experience outlines the importance of a 'high-tech' approach — continually updating community on research progress through email newsletters and text messaging, summarising results in videos, publishing open access and sharing links — as it builds transparency and equality via online deliberation, allowing for distributed discussion over the course of days, weeks, months and can encourage discussion of sensitive topics through anonymity. In this sense, facilitators for 'high-tech' web-based platforms are important as they allow: a) broad outreach, for example, to those who can't travel, speak or are shy/introverted; b) recruitment of larger sample sizes; c) rapid collection of data and input plus metadata, as demographics allows for sample stratification and more complex analytics; d) discussion of research findings through Twitter (Live Tweet Chat), which allows outreach to a broader audience through retweets and hashtags; e) generally cheaper and easier to organize (than in-person) meetings; f) potential for archiving, for example, video archive, documents, tweetstream. Barriers to 'high-tech' approaches are that: a) they are likely to over-represent younger, wealthier, better educated individuals with English as first language; b) there is greater potential for abuse by vested interests, vocal minority or 'trolls'; c) technical complexities may be unsatisfying or off-putting; d) it requires organizers and participants to have technical	(49,45,40,78,80,82,59,81,39,56)	High confidence	Context: USA Explanation: Moderate concerns regarding adequacy of data (data comes mainly fromm one primary (case) study that consistently represented other data expressed in other textual wording from other studies).

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expertise, software, equipment; e) they may not foster the strength and intimacy of relationships generated through in-person ('high-touch') meetings; f) less of a 'filter' in interactions and permanent record may invite unexpectedly harsh criticism and visibility; g) they may be limited in the ability to validate patient-reported diagnoses.			
CONSULTATION MODEL			
The community-based participatory research (CBPR) approach enables the identification of the community's needs. For so doing, however, appropriate research tools need to be designed, preferably with the help from the community itself. Surveys were used as part of the CBPR approach. Thus, one key barrier to social engagement was a low participation of community members in the design of survey instruments, as well as an artificial adjustment between survey instruments and the characteristics of the community. Additional barriers would be: power struggles between stakeholders, lack of funding and infrastructure, uneven receptiveness from the community, lack of goal-sharing among stakeholders, and community mobility. Therefore, research instruments need to be in tune with local characteristics, including ethnic characteristics. Other factors facilitating the collection of information are: partner input in intervention design, shared learning between academic and community partners, and bridging people on research teams. It is also necessary to understand the communities' level of health knowledge. For so doing, it is important to consider the community's specificities, especially when ethnic groups are focused on. Tools that facilitated the collection of information included surveys, forums, and photos.	(39)	High confidence	Context: Africa, Bangladesh, China and India Explanation: Minor concerns regarding adequacy of data (data ccomes mainly from one systematic review and there is no specific data extracted that could build this finding for each country in Africa as well as for Bangladesh, China and India).
Regarding recruitment strategies for both Consultation and Participation Models, it is important to observe the three profiles of social representativeness: citizens ('pure'/naïve public) provide democratic accountability and receive information from sponsors of health technology development, assessment and policy/decision-making organisations as subjects of education and empowerment strategies; consumers (affected public) provide subjects for knowledge exchange and give information to sponsors and are, therefore, educating/enabling experts to reconsider and enlarge their views with first-hand knowledge about life under specific conditions; advocates (partisan public) provide strategic input as to potential competitors, barriers and enablers to specific policy goals, engaging in information exchange with sponsors about the landscape of potential arguments raised by such expert consumers and/or technical experts. Furthermore, despite recruitment strategy (purposive sampling, (non-)stratified random sampling (electoral roll, random digit dialling, commercial database of registered telephone numbers, national polling institute), professional and/or market research sampling, newspaper advertisement, word-of-mouth/advertising through networks and/or community organisations (to reach specific disadvantaged and underserved populations, government departments or existing citizens' council), it is important to: a) stratify variables (age and sex (all studies) geographic area (one); race/ ethnicity and education, at least one of employment status, housing tenure, religion and occupation, socioeconomic status, income, social class, car access, health parameters, children and language) to avoid bias and skewed sampling; b) consider duration and timing; c) consider honorariums. The aim is to reflect on transferability of findings to specific populations, such	(49,104,40,15,61)	High confidence	Context: Australia Explanation: Minor concerns regarding adequacy of data (data comes mainly from two systematic reviews).

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as people from rural or remote areas and/or specific language speakers.			
As direct strategies for social engagement processes may be time- and additional resources-consuming, and recruitment and representativeness may also be difficult, the Australian experience illuminates the beneficial roles for colloquial evidence (those from informal webpages and personal blogs) in eliciting citizens' and/or consumers' qua patients' perspectives and experiences to inform health technology development, assessment and policy/decision-making processes. Many consultation approaches could be used effectively to elicit the community voice, such as deliberative polls, surveys and consultative focus groups, however, these approaches are often conducted in the later stages of the HTA process and/or independent from a specific HTA, and their effectiveness is moderated by contextual and environmental factors, as well as by the perceived legitimacy of the method from the viewpoint of the decision maker. In this sense, meaningful and cost-effective social engagement may be considered uncertain. Therefore, when evidence is of good quality, direct social engagement may not be necessary and three broad methodological approaches for introducing ethical and social issues into HTA reports have been outlined by the Australian experience, namely: seeking expert advice from bioethicists and social scientists, conducting qualitative and quantitative primary research, and performing secondary research that includes published literature on social and ethical issues.	(49,104,15,61,59)	High confidence	Context: Australia Explanation: No concerns for all CERQual components.
Focus groups constitute a cost-effective consultative strategy to elicit comments from the public as another form of evidence to identify issues that really matter to patients, such as the impact of health technologies in quality of life. It is important to pilot test focus group guides with moderators (facilitator and observers who will take field notes on the group discussions and dynamics). It is also important to provide contextual information to participants prior to group meetings so they can prepare — vignettes have been pilot tested for an Australian HTA process and were effective to give participants an idea as to the content and process of Australian HTA, and to stimulate discussion.	(104,61)	High confidence	Context: Australia Minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies).
From the Australian experience, questionnaires and surveys are another method for consultation that have been used in Australia to measure the level of empowerment of individuals with excellent cost-effectiveness.	(40,61,59)	High confidence	Context: Australia Explanation: No concerns for all CERQual components.
Consultation is deployed, at the national level, for purposes of policy-making. This is done by means of interviews, questionnaires, focus groups, and dialogue meetings. These initiatives were impaired by the attitudes of the HTA agency itself, whose decision-makers were not completely willing to understand the patients' needs, in addition to being likely to be get involved in corruption schemes. Facilitators to the process were: stimulation of mutual learning between stakeholders, development of a shared definition of problems and causes, and the joint formulation of possible solutions.	(64)	High confidence	Context: Benin Explanation: No concerns for all CERQual components.
The viewpoints of participants were grasped in the framework of citizens' juries. Some people were responsible for taking notes. Other forms used were: audio recording, video recording, voting, participant diaries, questionnaires, jury reports, and interviews. This information was analysed by means of qualitative data analysis techniques.	(40)	High confidence	Context: Brazil Explanation: No concerns for all CERQual components.
It is important to assess participants' anxiety (worries) as a quantitative outcome measure of	(49,28,65,40,38,73,74,29,101,	High confidence	Context: Canada

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the cost-effectiveness of social engagement strategies. Furthermore, measuring their level of understanding of health issues and motivation to participate (mobilisation) is a way of adequately designing and planning resources for effectively developing and implementing social engagement strategies. Most importantly, the Canadian experience outlines the need to identify needs unique to each ethnic community and underserved, hard-to-reach populations as, by enhancing the relevance of health promotion messages that address health disparities amongst multi-ethnic populations, fostering improved health behaviours and overcoming cultural and access barriers, social actors may be sufficiently encouraged to participate in social engagement processes. • **As the Canadian experience with social engagement activities has been to prioritise the Participation Model as a way of seeking informed social views using more democratic, deliberative processes, Consultation methods such as opinion polls, surveys, in person, online (e-Health, e-mail) and telephone interviews, focus groups and voting should be used as a way of both eliciting and collecting more detailed feedback data from each participatory activity throughout the engagement strategy to: a) develop recommendations, patient information leaflets and guidelines that wins previously observed implementation barriers to (new) health technologies within health systems, nationally and locally; b) support and promote the transparency and legitimacy of the engagement activity further stimulating adherence of citizens/consumers qua patients (and families/carers/legal representatives) and advocates as well as compliance of engagement implementers, institutionally. In this sense, consultation methods have been used, prior, during and after participatory strategies as a way of:** **a) recruiting participants (statistical social representativeness grants legitimacy to consultation processes when large groups of populations are to be recruited, therefore it is important to keep consultation process open until it is achieved);** **b) profiling participants (it is important to gather information such as age, gender, geographic area, race/ethnicity, education, income, employment status, housing tenure, religion and occupation, socioeconomic status, income, social class, car access, health parameters, language and family structure (including number and age of dependents), potential affiliations with special interest/patient advocacy groups and employment in a health-care delivery organisation or government as a health-care professional to consider potential exclusion/ineligibility criteria for participation);** **c) collecting credible information and knowledge about contextual (national, local, regional) and populational (individual, familial, community) priorities for improvement of health technologies implementation at national and local levels;** **d) test information materials prior to dissemination and/or during the engagement process.** • **Self-administered surveys can be designed to elicit social values or distributive preferences for health care across the population and can include: ranking, rating (Likert-scale) and choice-based (choice-based conjoint analysis) questions – each type of question incorporates identified factors and/or participants' characteristics around which**	69,39,55,67, 56,28)		Explanation: No concerns for all CERQual components.

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distributive social preferences have frequently been sought such as: current health or severity of illness; imminence of death; age; health improvement or gain with the technology. Post-engagement and follow-up surveys are also an interesting tool to evaluate more procedural elements of the participatory activities, as health professionals and decision-makers implementing the engagement process can identify institutional expectations around social representativeness, quality of engagement activity, responsiveness of participants and of deliberative processes to design new and/or improve current practices. • **Interviews (in person or online — e-mail and/or e-Health) can be used independently and/or before/after questionnaires to either collect and/or confirm information elicited via other consultation methods with the aim of requesting individual, more in depth comments on perceptions, attitudes and additional information regarding individual, familial, community impact of using health technologies within the contexts they are embedded in. Therefore, it is important to profile consultation and participation implementers and implementees to better distinguish statistical representativeness of a group from the representation role of individual participants, since the logic of both indirect (consultation) and direct participation in group decision-making is mainly one of representation, in which individual participants are asked to speak for a wider constituency, granting legitimacy to the engagement process. In this sense, as there is need to not only involve all stakeholders with an interest in health technologies – on a case-by-case manner – but also for less cumbersome participation processes that allow for more flexibility in their design and implementation, avoiding purposeless large, structured, formal and sometimes confrontational consultation processes that are conducted in a similar manner across most health technology assessment organisations, it is important to experiment with new consultation methods such as photo voice, public hearings and other approaches that encompasses social media use to foster the establishment of partnerships amongst citizen/consumers qua patients (and families/carers/legal representatives) and advocates with health professionals and social engagement implementers. The Quebec public hearings are large, structured, formal and sometimes confrontational consultation processes that are conducted in a similar manner across most boards, where selected participants are provided with information packages on the issue and asked to submit written responses that are presented at the hearing for commenting that are then compiled and analysed by staff before recommendations are made for a final decision. Decision-makers see the advantage of the hearing in its ability to get the proposals out to the region and to obtain feedback about them. Participants in these public hearings are typically drawn from interest groups active in the health- and social-services fields and may be limited by the board's views of which groups have an interest in a particular issue, traditionally used for decisions concerning service-delivery planning and health priorities-setting for the region. Quebec decision-makers also use issue forums, where a small group of individuals gather to discuss and debate specific issues, regional workshops, surveys, focus groups and private meetings. Barriers to consultation have been: difficulties in**			

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mobilising the population due to consultation fatigue; short timelines and limited resource; political interference (either from ministerial interventions or interest groups can and often does undermine the legitimacy of a consultation process — experience of many regional health authority decision-makers through the health-services restructuring period as carefully planned consultation processes were cut short, delayed or overtaken by central government, which left the local health authority looking weak and incompetent); characteristics of the decision itself also seemed to influence the extent to which meaningful consultation could take place; complex, technical or controversial health-care policy decisions posing significant challenges to public engagement.			
Citizens state their preferences by means of rankings or simple choices. This process is based on the provision of information, which should not be excessive to the point of becoming confusing. Aspects that facilitate a well-informed choice: high educational levels, adequate institutional support, provision of information about the rights of choice, awareness of the full repertoire of potential types of information, awareness of the full repertoire of available ways of sorting and ranking.	(75)	Moderate confidence	Context: Chile Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one primary (case) study).
Citizens were interviewed (structured interviews) or invited to manifest their preferences by means of choices and rankings. Factors that facilitate the manifestation of viewpoints include: high educational levels, institutional support, a focused selection of participants, the realization of induction days, and appropriate settings for interviews.	(75,49,52,67)	High confidence	Context: Denmark Explanation: No concerns for all CERQual components.
Methods such as questionnaires, surveys and benefit-risk analysis are outlined amongst other methods for eliciting preferences from various stakeholders — such as: discrete choice experiments (DCEs), analytic hierarchy processes, multicriteria decision analysis (MCDA), Bayesian statistical model (probabilistic/Markov simulations), decision trees and influence/relevance diagram — an other methods to be used jointly — such as: Kaplan-Meier estimates, Quality-Adjusted Life-Years (QALYs)/ Disability-Adjusted Life-Years (DALYs), conjoint analysis — since no single benefit-risk methodology can fully capture all aspects of a benefit-risk assessment, therefore a combination of methodologies should be matched to the complexity of the problem. The EUneHTA experience identified a few facilitators to the implementation of such types of consultation methods, namely: a) that it may be helpful to view social engagement in a non-hierarchical/non-linear way (information, consultation, participation, and empowerment); b) focus on training and competence-building to equip citizens with the skills, confidence, and capability to participate meaningfully in the city's decision-making processes; c) emphasis on participatory research; d) development of cohorts of community leaders empowered to enhance social engagement; e) focus on peer support and mutual aid as methods of building self-esteem and individual empowerment within communities of interest; f) use of visioning, drama and other creative techniques as processes that are in themselves empowering, but which also empower people to imagine and shape the future; g) focus on specific disadvantaged sub-populations often linked to thematic priorities. • **Benefit-Risk Analysis: representatives are involved in oral discussions on benefit-risk evaluations through participation in expert group meetings and scientific advice/protocol**	(90,58)	Moderate confidence	Context: EUnetHTA Explanation: Minor concerns regarding methodological limitations and serious concerns regarding adequacy of data (data comes mainly from one theory-based primary study).

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assistance procedure when deciding on the approval of drugs and medicinal products, the risks and benefits of different interventions are to be considered in the decision; • **Bayesian Statistics: focuses on valid inferences from evidence, providing probabilities — the data used to calculate the significance levels can be used to determine relevant posterior probabilities for decision models; problem — do not generally deal with multiple criteria but, when integrated into decision models that do include multiple criteria, probabilities are an essential ingredient for sound regulatory decision making both preapproval and post-approval;** • **Decision Trees and Influence/Relevance Diagrams: models derived from decision theory particularly applicable to unique situations, and can integrate data from many sources, value or utility judgments — problem (decision trees): can expand exponentially as more and more nodes are included, thereby becoming very complex — care and experience are needed to ensure a realistic representation of the problem facing regulators in building these diagrams, and some problems are too complex for decision trees; Markov Simulations extend a decision tree to include the movement between health states over time, but most relevant for post-approval decisions;** • **Discrete-Choice Experiments (DCEs): a stated-preference method whereby preferences are usually assessed through choices from hypothetical alternatives in a survey setting. DCE re being used to reflect patient values and preferences for clinical outcomes in HTA assessments from a larger sample size than the patient or expert testimony alone allows. An increasing number of HTA agencies are looking into the most effective way of incorporating patient preferences into their decision-making processes. Some challenges with using patient preference data in HTA have been identified. As HTA focuses on pricing/reimbursement decisions and not individual treatment decisions, some researchers suggest that HTA should focus on preferences of the public or payer and not patients. Overcoming these challenges, patient preference data can show different scenarios and potentially highlight associated cost-effectiveness models to further quantify indirect costs;** • **Multicriteria Decision Analysis (MCDA): logical, coherent model for decisions with multiple objectives, comprehensive in its ability to accommodate all forms of data and time preferences, and provides a way of transforming input data into values (or utilities); MCDA as an approach to support benefit-risk assessment; full MCDA model would be most useful for difficult or contentious cases that could arise when the benefit-risk balance is marginal and could tip either way depending on judgments of the clinical relevance of the effects, favourable or unfavourable, and in the case of many conflicting attributes — proposed as a way to overcome some of the problems of common benefit-risk assessments as basis for authorization decisions;** • **Kaplan-Meier Estimates of changes in health conditions over time: relevant to displaying changes in health states over time — can be used in Markov Model or Decision Tree, and can incorporate the utilities of the health states; Kaplan-Meier Curves are one way of displaying the results of a Markov Model or Decision Tree with repeating event nodes at each time period;**			

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• **Quality-Adjusted Life-Years (QALYs)/ Disability-Adjusted Life-Years (DALYs) for the modelling of multiple end points: QALY is a widely used measure of both quantity and quality of life — benefit for health care evaluation: applicable to all indications and can therefore be used to compare interventions across diseases and programs; DALY is a summary measure of population health widely used in disease burden assessment and represents the incident number of healthy life-years lost because of disease or disability — current focus on health outcomes restricts the relevance of both DALYs and QALYs, but because they are multi-criteria metrics, they could be developed for both regulators and health technology assessors;** • **Cojoint Analysis (CA) to illustrate trade-offs between favourable and unfavourable effects, especially to determine patient preferences: real or hypothetical treatments are described using various features and patients are asked to indicate their preference for them; based on their responses across multiple comparisons, it is possible to calculate overall preferences or 'utility weights' for various treatment features using multiple regression — particularly relevant to eliciting patients' preferences but does not consider uncertainty.**			
The Analytic Hierarchy Process is used to grasp preferences and values in complex decision-making contexts. Focus groups and face-to-face interviews were also used, not only with patients but also with relatives and caregivers. By identifying the perspectives of those different actors, it is possible to promote a perspective where patients' views are considered as colloquial evidence that complement the scientific knowledge of experts. Here the main challenge is to arrive at an appropriate selection of participants and make the discussions clear to everybody. On the other hand, those processes enable the engagement of carefully targeted patients and the exploration of carefully selected topics.	(54,49,37,30)	High confidence	Context: Germany Explanation: No concerns for all CERQual components.
HTAi has been fostering deployment of robust (secondary) data from systematic reviews and other types of evidence synthesis and primary research, as evidence on citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives can be derived from both quantitative and qualitative approaches. Robust (secondary) data collection can also come from evidence submissions, as patient organisations often collect information from citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' groups that they do not put in the public domain but that they may be willing to share it with researchers; therefore, it is important to establish a process for requesting submissions of evidence from such organisations to answer specific questions using qualitative or quantitative information, such as: a) overview of organisation; b) number of patients affected; c) experience with currently available therapy (perceived advantages and disadvantages; d) preferences and needs (met and unmet); e) information to explain how the health problem affects patients/carers; f) potential impact of new technology (how it matches up to users' needs and preferences, advantages/disadvantages over current therapy, impact on lives of patients and carers); and g) similarly to all other contributors, citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' organisations should be asked to provide evidence sources and declarations of interest. The HTAi experience has identified a series of barriers to the implementation of consultation via	(14,63)	Moderate confidence	Context: HTAi Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one (non-systematic) review and a qualitative primary study).

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secondary data collection, such as: a) HTAs have limited access to expertise in the social sciences; b) time and cost to citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' engagement in HTA — decision-making bodies are often happy to commit substantial resources to ensuring that these elements are robustly assessed, but they are not willing to fund research to robustly determine societal perspectives; c) there is no clear guidance for HTA agencies on how to develop and implement social engagement activities but the HTAi Interest Group on Patient/Citizen Involvement in HTA will continue to provide material to support this process; d) without sufficient social engagement, there is a risk of HTA findings being rejected as a result of societal/political pressures. A series of facilitators have also been identified by the HTAi experience, namely that: a) HTAs should focus on societal problems, collect societal perspectives, and accommodate societal preferences, while allowing social participation in the HTA process as means to empower the citizens/consumers qua patients (families, carers, legal representatives) and advocates develop a sense of ownership in the evaluation and decision-making process (essential as the health systems that HTA is seeking to inform strive to ensure that decisions are made in partnership between health professionals and patients); b) HTA should go beyond the consideration of clinical and cost-effectiveness, to assess robust evidence about the perspectives of the ultimate user/receptor of the technology that can enlighten the social and psychological issues related to the real-world use of health technology; c) transparency about the influence of citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives in the deliberative process is essential; d) professionals' experienced in social/humanistic research should be responsible for gathering evidence about citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives and its presentation and interpretation in the HTA, therefore, the HTAi recommends greater collaboration between the HTA community and researchers; therefore, it is essential to call for more researchers from the social sciences to be employed in HTA bodies to balance the plethora of economists that seem to dominate and avoid qualitative evidence simply because they equate the word qualitative with descriptive or anecdotal, which is far from the mature and dynamically responsive field of qualitative research to changing society and perfectly suited to asking questions related to people's experiences with using technologies in health. • **Secondary data collection starts with literature searching to find valuable evidence about citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives, as they may arise from a variety of forms of studies in the social and humanistic paradigm, including qualitative studies (e.g., anthropological/ sociological/ nursing studies) and qualitative evidence embedded within quantitative studies. Literature search for qualitative evidence should be wide ranging and follow up on footnotes and reference lists, hand-search relevant journals and 'grey literature', and search by author name; evidence may also be found from websites of national patient organisations — search of journals will often include some related to the disease/condition or form of technology under investigation and other general sources of qualitative research, such as:**			

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The Patient; Health Expectations; Value in Health; Medical Anthropology Quarterly; Social Science and Medicine; Culture, Medicine, and Psychiatry; Anthropology and Medicine; and Sociology of Health and Illness. Next step is the assessment of qualitative research when, as with other (quantitative) systematic reviews, the quality of each study should be assessed using pre-specified checklists[1] or by criteria specifically developed by the researcher — quality assessments should evaluate the following: a) purpose of the study and relevance to study question; b) context (population/ setting/values comparable?); c) appropriateness of methods; d) transparency of data generation, analysis, and interpretation (avoidance of bias); e) connection between research question and conclusions (internal consistency); f) the account of the knowledge generated given the methods (relevance for practice). Synthesis of qualitative data is more exploratory and there are various methods with specific purposes as the synthesis may seek to interpret studies rather than merge or generalise them (e.g. meta-ethnography is useful to look for a new theory or 'line of argument' to explain all the studies), and/or may seek to go beyond a summary of research findings to generate new insights (e.g. narrative analysis). As these analyses are specialized and it is important that they are performed by an experienced researcher who is fully involved in the conclusions that are drawn from this work and the implications for the rest of the HTA. When assessing primary research, it is important to evaluate the research questions, purpose of analysis, the available resources, whether ethical approval is required for the research and to ensure that participants in the study give fully informed consent, if required. • **Primary studies using qualitative methods to understand citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives are most relevant when the goal is to get in-depth knowledge about the value and impact of a specific technology on the life of such populations. Most commonly used qualitative methods for generating evidence to determine citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives are individual in-depth and focus groups interviews — participant-observation can also be useful, as what people say they do, and what people actually do, can be in contradiction (also useful for gaining an understanding of the physical, social, cultural, and economic contexts in which patients live or are receiving care, therefore, data generated through participant observation in a real life setting (field work) can complement the subjective information reported by participants). New opportunities for qualitative research that are emerging with the advent of social networking regards the identification of social views from weblogs (use of such material requires the same considerations of quality and generalisability as more formal research).** • **Primary studies involving quantitative methods are most commonly used if there is limited time for input and research questions are clear, when evidence on citizens/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives has been found but there is a need to test findings in the specific/national regional context, to input to a cost utility analysis, and to address issues of generalizability and support triangulation of evidence. Quantitative data on citizens/consumers' qua patients' (families, carers, legal**			

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representatives) and advocates' perspectives can be generated from survey questionnaires administrated to a sample of specific stakeholders from the target population — questionnaires should be as short as possible with clear and precise questions, including relevant responses people could give; use of validated questionnaires will improve the robustness of results). Several internationally validated generic instruments exist for measurement of health status in any condition (e.g., EQ-5D, SF-36) and, for some diseases, specific instruments to measure quality of life have been developed and validated. New bespoke questionnaires to measure health status can be developed, but these need to carefully developed and fully validated, involving citizens/consumers qua patients (families, carers, legal representatives) and advocates in the development and piloting to ensure it is understandable (comprehensive, complete, and accurate listing of the target population to determine the best sampling method; the collection of data in the clinical setting has to be well organized according to the chosen form of survey administration, providing letters to present the research and a deadline for feedback). Incentives, short questionnaires, and sponsoring by credible organisations can help to improve response rates.			
Questionnaires and surveys were used. Here the main goal was to assess the community's empowerment through a specific questionnaire (Diabetes Empowerment Questionnaire). In addition, surveys were used in the framework of the CBPR approach. These surveys need to be flexible in order to capture the community's needs and are ideally designed with the help from the community. To collect information, video recording, surveys, and forums were used.	(59,39)	High confidence	Context: Iran Explanation: No concerns for all CERQual components.
Consultation is practised, at the national level, in the context of HTA. Participants could volunteer for a citizen consultation guided by a facilitator. They were invited to express their feelings and hopes towards the future of Europe. Difficulties included: the formulation of a final view which would not reflect the facilitator's preference; the expression of every participant's views; and the failure to include every type of opinions. Facilitators included: the carefully designed selection procedures; and the writing of individual statements by participants. Eventually, the event was successful and managed to collect unbiased opinions.	(85)	Moderate confidence	Context: Ireland Explanation: Serious concerns regarding adequacy of data (data comes mainly from one primary (case) study).
The conduction of mini-publics enabled to grasp the public's views. In health parliaments, some participants prepared position papers, and groups of participants prepared a summary of their views and recommendations, including divergent perspectives. Discussions were transcribed and transcripts were made available.	(34,86)	High confidence	Context: Israel Explanation: No concerns for all CERQual components.
Face-to-face data collection techniques (interviews) were used. Convenience and purposive sampling strategies were adopted. Information was stored by means of audio-recording or note-taking. For data analysis, a thematic analysis was conducted. The public's view is framed as colloquial evidence that can complement other kinds of evidence.	(40,30)	High confidence	Context: Italy Explanation: No concerns for all CERQual components.
Two substantive roles generally considered for social participation are considered in HTA, which includes: a) eliciting social perspectives to inform HTA, there are three broad methodological approaches for introducing ethical and social issues into HTA reports – seeking expert advice from bioethicists and social scientists, conducting qualitative and	(49,41,30)	High confidence	Context: Netherlands Explanation: Minor concerns regarding adequacy of data (data comes from two primary (case)

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quantitative primary research, and performing secondary research that includes published literature on social and ethical issues; b) appropriate setting and timing of consultation activities (easy walking distance and convenient day of the week). The Dutch experience also outlines the importance of deploying convenience and purposive sampling strategies along with face-to-face data collection as, in consultation methods, people take part in a research study by providing data (e.g. in surveys or qualitative research interviews) that is seeking societal views to influence decision-making. The Dutch experience has also identified a key facilitators to the implementation of consultation methods, as societal perspectives can be viewed as 'colloquial evidence' that provides additional knowledge and has a different role to that of other types of evidence; hence, this type of knowledge should not be judged in the same way as other evidence because it is not collected in the same rigorous and systematic manner.			studies and one systematic review)
(Online) ranking and choosing techniques fail when the issue at stake does not fit ranking approaches, or when the ranking proves too complex. On the other hand, such techniques lead to good results when the educational level is raised, or when more detailed information is provided. In addition, patients' or the public's perspectives were elicited through some research methods, namely: expert advice from experts from bioethicists or social scientists; the conduct of primary research (including interviews); and the conduct of secondary research (including literature review of ethical and social issues). In the framework of citizens' juries, meetings were recorded and, in some cases, a final jury report was elaborated. Even thought recruitment is complex and time-consuming, and the issues discussed maybe be too complicated for lay people, such consultation activities are still valuable when people are provided with information and the discussion is carefully framed.	(75,49)	High confidence	Context: New Zealand Explanation: No concerns for all CERQual components.
Web-based support to citizen choice (prioritization) are used as part of e-Health initiatives. This method comprises an information model – Isolation (provision of technological devices that describe the framework for choice of, for example, a primary health care provider or a school, and the search for available units) and examination (provision of technological devices that investigate and compare available choices based on, for example, waiting times and quality indicators) – and a consultation model – ranking (provision of technological devices for sorting and choosing among selected alternatives) and choosing (IT-supported choice / preference elicitation). The Norwegian experience identified a series of barriers to the implementation of this type of consultation method for web-based preference elicitation, such as: a) design of cases does not support ranking as it may be perceived as controversial (as it points to the 'best' and the 'worst' alternatives in a very obvious manner, it influences the activities of those who are ranked by causing them to try to improve their position by manipulating or concealing information, and it affects which options (e.g. service providers) are shown when there are multiple options available); b) abundant information, which cannot be used in ranking, may influence choice negatively due to more confusion, rather than simplification; c) contradictory role of public authorities in providing clear messages for choice. The Norwegian experience has also identified a series of facilitators to the implementation of such consultation method, namely: a) there are differences to be used	(75,30) *Updated (14 Nov 2019)	Moderate confidence	Context: Norway Explanation: Minor concerns regarding methodological limitations and adequacy of data (data comes mainly from two primary (case) studies).

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by designers interested in understanding how calculated choice may be supported for the following processes – isolation (differences exist as far as the availability of information about rights and in the search devices for alternatives), examination (differences exist as far as the kind and availability of information and the types of devices for making comparisons) and ranking (differences exist in the outlay of available alternatives, and in the support for choice); b) provision of information about the right of choice is important; c) awareness of the full repertoire of potential types of information is important (extensive amounts of information can be provided about available options and opportunities via Web-based decision support – for example, in numeric, textual, or graphic form ["format"], using neutral information (vs. marketing information), information about present circumstances (vs. future opportunities), and user evaluations from official investigations (vs. more personal evaluations of opportunities ["aim"]); d) awareness of the full repertoire of available ways of sorting and ranking is important due to risk of information overload in choice situations – providing comparison devices for use in selecting alternatives is necessary; however, making comparisons of long columns of data on relatively few alternatives may still be unsatisfactory — user preferences on service options and opportunities for certain aspects or types of information can be highlighted before users examine a few selected alternatives; or sorted lists can be prepared for users based on these preferences; e) ranking can be achieved by presenting graphic information and examples as well as by sorted lists.			
Information technologies (eHealth) were also used, so people could rank their preferences (IT-supported choice). Citizens must be well-informed about their right of choice. In the framework of stakeholder conferences, participants were asked to send written information to the health department of their country council. Barriers to this scheme were: the complexity of the issues at stake, which do not fit into simple yes-no options; the unavailability of relevant data; and complexity of information. The main facilitators were: high educational level; and support given to citizens.	(75,94)	High confidence	Context: Sweden Explanation: Moderate concerns regarding adequacy of data (data comes mainly from two primary (case) studies).
The UK has successfully experimented with and implemented a series of methods, such as (ranking, quality of life [QoL], discrete choice, priority-setting) online questionnaires/surveys, (in-depth, individual, structured, open-ended questions, in person, online, via e-mail, telephone) interviews, focus groups, conjoint analysis exercise, observations of citizens council session, document analysis, vote counting (comparison amongst health professionals, HTA implementers, decision/policy-makers with citizens/consumers qua patients and their families, carers, legal representatives, as well as advocates). Consultation methods for social engagement in HTA is meant to eliciting social perspectives to inform HTA on three broad methodological approaches for introducing ethical and social issues into HTA reports: a) seeking expert advice from bioethicists and social scientists, b) conducting qualitative and quantitative primary research; and c) performing secondary research that includes published literature on social and ethical issues.	(75,49,34,91,105,44, 40,94,59,98,95,92,46,96,9,39, 67,30,56)	High confidence	Context: UK Explanation: No concerns for all CERQual components.
Questionnaires and surveys have been broadly used to assess people's level of empowerment and to measure quality adjusted life years (QALYs). Nevertheless, a series of barriers to their implementation have been outlined by the UK experience, such as: a)	(49,34,105,40,94,59, 92,96,39, 30,56) *Updated (14 Nov 2019)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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weakness of reliance upon quantitative methods and approaches in data collection and analysis; b) public preferences are not immediately accessible and are open to manipulation by the way questions are framed; c) resource constraints within which consultation has to be conducted inevitably implies striking a balance between eliciting considered preferences from a small well-informed group and eliciting less well considered preferences from a larger, more representative, sample; d) design of cases does not support ranking as — d.1) it may be perceived as controversial because it points to the "best" and the "worst" alternatives in a very obvious manner; d.2) it must be based on available data rather than on unavailable data that may be still more relevant; d.3) it is also a controversial issue because the available data may be unclear about new service providers; d.4) it influences the activities of those who are ranked by causing them to try to improve their position by manipulating or concealing information; d.5) use of ranking technologies can also affect which options (e.g., service providers) are shown when there are multiple options available; e) abundant information, which cannot be used in ranking, may influence choice negatively (more confusion, rather than simplification). The UK experience with questionnaires and surveys for public consultation also listed a series of facilitators to their implementation, such as: a) provision of support by private agencies — agencies that work in cooperation with public agencies (i.e. they take an active part in what we usually see as the technological construction of the relationship between the state and the individual) constitutes an 'e-Government' initiative that is often implicitly assumed to be an area for public agencies only; b) differences to be used by designers interested in understanding how calculated choice may be supported in Ranking (outlay of available alternatives, support for choice); c) awareness of the full repertoire of available ways of sorting and ranking is important due to risk of information overload in choice situations (providing comparison devices for use in selecting alternatives is necessary; however, making comparisons of long columns of data on relatively few alternatives may still be unsatisfactory — user preferences on service options and opportunities for certain aspects or types of information can be highlighted before users examine a few selected alternatives; or sorted lists can be prepared for users based on these preferences); d) visual aids for ranking (graphic information and examples by sorted lists). In this sense, there is an important role for qualitative work in this are at three levels: a) at the questionnaire design stage, in depth discussions with potential respondents would help to explore the extent to which there is misunderstanding in the way the questions are framed, and such discussions could investigate whether true preferences are being accessed by the questions posed; b) qualitative work at the preference elicitation stage might allow more considered and well-informed preferences to be revealed, especially if that were to happen as part of a group exercise; c) qualitative methods have an important role in the interpretation of the results of questionnaire-based studies, in terms of helping to understand the meaning of the results and to begin to explore the factors that are driving the results.			
Regarding surveys and focus groups, Primary Care Groups (PCGs — introduced in 1998) implemented a specific Consultation approach, as PCGs were obliged to engage in a two-way	(49,34,105,40,94,59, 92,96,39,30,56)	High confidence	Context: UK Explanation: No concerns for all

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process with local communities, both to disseminate information about PCG decisions and to receive views that might inform them. PCGs also deployed a number of methods — most frequently, had developed active consultation through local networks and through surveys or focus groups with the public — these tended to be less common, since the most frequent activities were concerned with dissemination of information. In April 2013, when local Clinical Commissioning Groups (CCGs) in England assumed responsibility for purchasing NHS care from Primary Care Trusts (PCTs), a public consultation document formed the basis of the process and included questions for members of the public to respond to in writing — this document described how the proposed service changes were developed by the local CCGs, made up of GPs representing the PCTs, working with 'hospital doctors, nurse leaders, providers of community care, social services, patient and volunteer groups and charities'. Document also contained a range of reasons established by commissioners on why they believed local services 'needed to change in order to improve quality'. Throughout the documentation, particular emphasis was placed on the fact that the plans had been developed by local clinicians — many of these individuals had worked in the area for a long time, and thus it was argued that they understood the local health care economy very well. Documentation also explained that a range of challenges threatened to impact the delivery of patient care locally: growing and ageing population; insufficient numbers of specialists in hospitals to provide round the clock care; inadequate NHS facilities; and increasing financial pressures on the NHS. Commissioners sought public views about a range of options aimed at consolidating care on few sites, to make better use of staff expertise, buildings and funds. Documentation was distributed across the area to GP practices, libraries, hospitals and other health sites, pharmacies, patient groups and local authority offices. The main consultation document was supplemented with a number of other publications, including factsheets about changes to specific services; answers to frequently asked questions; and a public letter outlining the support of senior local clinicians. Barriers to this type of consultation method included the impact on commissioner approaches to consultation: a) commissioners emphasised that the plans had been developed by local clinicians, many of whom had worked in the area for a long time — however, there was little sense that many of the participants acknowledged that the proposals were clinically-led, or considered this to be important (most simply referred to the decision-makers behind the plans as an anonymous 'them'); b) many of the 'lobbyists had engaged with the commissioners directly, as commissioners behaviour at the meetings had created the impression for some attendees that the public's concerns were trivial and irrelevant; therefore, commissioners are encouraged to use an 'expert' to present the case for change, usually a senior clinician, whose view (it is thought) will carry weight with the community (reason for scepticism was that many viewed the proposals as aimed principally at cutting costs, rather than improving patient care — a perspective that is often shared by members of the public when such changes are proposed); c) commissioner's failure to attend the public meetings and engage in discussion led participants to question whether or not the individuals putting forward the proposals could be trusted; and d) holding public meetings at prominent venues, where			CERQual components.

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refreshments are provided also impacted on the perception that the meetings 'were not very genuine' (there was 'some soft soaping going on'). Barriers to this type of consultation method included the impact of consultation methods: a) complaints about the volume of documentation (80 pages long) provided by the commissioners, including the length of the feedback questionnaire (30 questions), and the way in which the consultation questions were posed; b) document was not transparent about the implications of the proposals for patients; c) phrasing of the questions was perceived by some to have excluded opportunities for the public to express disagreement with the plans (consultation questions to be leading respondents into agreeing with the proposals); d) disenchantment with the consultation process led many to dismiss the legitimacy of the commissioners' arguments (untrustworthy). In this sense, a noteworthy facilitator in dialogue is to consider the way in which risk is interpreted by the public within the context the consultation will be implemented. To re-establish trustworthiness, it is important for decision-makers to explicitly acknowledge and proactively address public responses to the consultation, as part of their 'conversation' with local communities. It is also important to explore the ways in which the public respond to both the method of consultation, and the content of reconfiguration proposals, which may help those planning reconfigurations in future.			
Regarding interviews as a Consultation method, it is important that public members of advisory panels' provide useful comment and encouragement of greater sensitivity to patient perspectives among other panel members, as they lobbied for particular patient groups. In this sense, HTA Organisations' staff had concerns about members' specialist backgrounds being inadequate for their generalist role on a panel, and about possible conflicting interests with their organisational role, whether professional or public, voluntary or paid, to advocate for patients in a particular area. Barriers to implementation were: a) no opportunity for communication to clarify or justify topics between people outside the HTA who made suggestions and people inside the HTA who processed them for priority setting during the consultation process; b) structural — understanding (HTA scope, tasks, implications of lay comments), matching (interests/priorities, roles, time scales for effective working) and capacity (financial, workforce, research and interpersonal skills); c) procedural — iterative and timely communication, reflective practice, face-to-face interaction. Facilitators to implementation were: a) capturing suggestions for research was less of a challenge where HTA Organisation staff took them from the recommendations of systematic reviews; b) need for 'relationship building' to 'improve dialogue' with people who might offer research suggestions; c) efforts to formalize working relationships with organizations by 'affiliating' them with the HTA; d) working with affiliated organizations as one possible way of 'nurturing and fostering' relationships that could lead to better suggestions; e) affiliated organizations were already relatively successful (8–9% of their suggestions leading to commissioned research); f) over time, skilled public membership might be changing the culture of advisory panels, with all members becoming more sensitive to patient/public perspectives.	(49,44,40,98,30,56) *Updated (14 Nov 2019)	High confidence	Context: UK Explanation: No concerns for all CERQual components.
Colloquial evidence as a Consultation method constitutes a type of informal evidence that	(40,95,30)	High confidence	Context: UK

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helps provide context to other forms of evidence in guidance development; despite challenges around quality, and the potential biases, as well as its use is becoming increasingly important in assessments where scientific literature is sparse and to also capture the experience of all stakeholders in discussions, including that of experts and patients (as part of active participation models in person and online). NICE´s Clinical Guidelines Program receives advice from clinical experts and citizens/consumers qua patients (families/carers/legal representatives) and advocates is obtained throughout the guidance development process through Guidance Development Groups (GDGs) that include health professionals and citizens'/consumers' qua patients' (families'/carers'/legal representatives') and advocates' representatives with relevant expertise and experience of the specific guideline topic at hand. NICE's Public Health Program deploys 'expert testimonies' who can once again be used as evidence, which are defined as 'short papers (with references to any relevant published work)' that reflect opinions of certain experts in the field when there are either significant gaps in the evidence, significant conflicts amongst available evidence, or in instances where there is the need for the 'views and experiences of specific groups' — some public health guidance can also undertake primary research as 'field work' to inform practice and test the feasibility for implementation of their draft recommendations with 'policy makers, commissioners and practitioners (including members of the community, volunteers, families, carers, legal representatives, advocates as well as professionals such as GPs, nurses, and teachers)'. All such programs have either a NICE Standing Committee or a Temporary Advisory Body such as a GDG that considers the evidence in a deliberative process that further generates colloquial evidence through its deliberation — a deliberative process has been defined as a process that 'provides guidance informed by relevant scientific evidence, interpreted in a relevant context wherever possible with context-sensitive scientific evidence and, where not, by the best available colloquial evidence'. Standing Committees have a general expertise and are not specialists in the condition of interest and so often get specialists, professionals, relevant commissioners and citizens/consumers qua patients (families/carers/legal representatives) and advocates to participate in the deliberation process by presenting their views at committee meetings. GDGs for the Clinical Guidelines Program have topic specific membership but can still have further co-opted experts if required for the deliberative processes — these deliberations are summarised within the 'considerations' or 'evidence to recommendations' sections (depending on the program) of the final guidance and act as a primary direct source of colloquial evidence. All guidance production at NICE follows the 'Patient and Public Involvement Policy' (PPIP), which sets the platform for the contribution of society, and organizations representing their interests, to the work of NICE — this enhances the NICE guidance, giving them a greater patient, carer, or community focus and relevance. Additionally, NICE's Citizens Council (group of 30 ordinary members of the public, representing the country) also have their views captured through reports that feed into the methods and processes across the Institute — although the decisions reached by the Citizens Council do not directly affect any individual piece of guidance, their views are responsible for ensuring the 'public perspective on overarching			Explanation: No concerns for all CERQual components.

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moral and ethical issues' and can be considered as another direct source of colloquial evidence. A few facilitators to the implementation of colloquial evidence into HTA processes have been outlined by the UK experience, namely that: a) three different types of evidence overlap and interact with each other (e.g., expert opinion could be based on knowledge of credible scientific evidence and at other times, in the absence of good external evidence, be limited to biased personal opinions); b) credible objective scientific evidence may exist but be over-ruled by poorly quantified and biased personal opinions, due to personal agendas and beliefs; c) NICE hopes that by having Standing Committees that hear arguments from both sides, or topic specific advisory groups that consist of members with opposing professional viewpoints, that individual biases are minimised; and d) colloquial evidence like any other type of evidence can be of varying quality and with certain level of uncertainty associated with it — maybe colloquial evidence should also be critically examined before its inclusion into any decision-making model.			
Whether consultation is via a 'high-touch' — through setting-up 1:1 in-person interviews with participants to get feedback on consent forms, questionnaires, research hypotheses, and/or key informant interviews to select study design and outcomes parameters — or via 'high-tech' approaches — by using social media platforms (e.g., Facebook), to allow voting on research priorities, and/or collaborating with eHealth communities (e.g., PatientsLikeMe, HealthTalk Online, Inspire communities) to develop studies using patient-generated data — the US experience has outlined the role of Consultation methods to measure the level of empowerment of populations. In this sense, questionnaires, surveys, focus groups and (open-ended, in-person/online/telephone) interviews have been used to elicit citizens'/consumers' qua patients' (families, carers, legal representatives) and advocates' perspectives to inform HTA. Within such scenarios, three broad methodological approaches for introducing ethical and social issues into HTA reports1: a) seeking expert advice from bioethicists and social scientists; b) conducting qualitative and quantitative primary research; and c) performing secondary research that includes published literature on social and ethical issues. Nevertheless, empowerment evaluation from social initiatives is not a simple endeavour. The US experience outlines that HTA sponsors/agencies as well as community-based organisations staff face multiple challenges in the evaluation of their empowerment programs, such as lack of time and lack of skill. Other barriers are: a) recruitment of participants is a sensitive and time-consuming issue (challenge identifying appropriate consumers; collaboration with consumer organizations may also be difficult due to very strongly held beliefs; lay people understanding of their role and issues); b) speed of discussions; c) unfamiliarity with the HTA process; d) use of technical language and acronyms; e) some tasks may be too technically demanding for citizens/consumers qua patients (families, carers, legal representatives) and advocates; f) participation in evaluation activities requires some specific abilities or skills (work in a multidisciplinary team); g) unfamiliarity of lay people with research needs; h) researchers' and HTA implementers' unfamiliarity with consumer organisations and their ways of working; h) time and additional resources required for consulting representatives of society. Despite these challenges, there	(49,45,78,80,59,81,39,56)	High confidence	Context: USA Explanation: No concerns for all CERQual components.

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are specific facilitators that provide a venue for the implementation of consultation methods, such as: a) focused invitations (i.e., inviting people who have experience related to the topic); b) citizens'/consumers' qua patients' (families, carers, legal representatives) and advocates' mentoring, training, support, and the presence of an induction day; c) well-defined outcome-focused presentation; d) appropriate setting and timing of consultation activities (easy walking distance and convenient day of the week); e) open working style and innovative culture in HTA organisations.			
Regarding health technology development processes, social engagement methods with potential end-users and other stakeholders, including citizens/consumer qua patients (families, carers, legal representatives) and advocates, using well-constructed questions, and possibly using Delphi-like procedures have been promoted at all levels. There is not an aim to empower such groups; however, the assumption is to include the widest range of populations as possible. Barriers to the implementation of Delphi-questionnaires for priority-setting identified by the WHO experience are: a) the use of summary burden of disease measures, such as disability adjusted life years (DALYs), have been criticised for focusing on disease rather than resource use and interventions, because of the assumptions about values inherent in such measures, and because of the technical limitations of such measures; b) important methodological issues need to be addressed to ensure that the procedure used is valid, reliable, consistent and useful for policy making; c) debates and limited data regarding social engagement in priority setting (from a small survey in Australia that the public overwhelmingly want their preferences to inform priority-setting decisions); d) avoid expecting nationally developed guidelines to cover every operational issue for every kind of setting, as guidelines that leave too much to be decided at the local level or during implementation run the risk of being ignored, misused, and modified in ways detrimental to patients — this is even more so for internationally developed guidelines. Facilitators to the implementation of Delphi-questionnaires for priority-setting identified by the WHO experience are: a) priority setting at each level should draw on the strengths and minimize the limitations of international, national and local organizations, so both centralised and decentralised processes that take account of these different strengths and limitations, as well as needs; b) the application of criteria for priority setting requires judgements, therefore, it is important to explicit criteria, to ensure that these judgements are made openly, and that they reflect the priorities of WHO's member states, particularly those of low and middle-income countries; c) criteria for establishing priorities should be applied using a systematic and transparent process, which also considered unmeasured factors because data to inform judgements are often lacking; d) groups that include stakeholders and people with relevant types of expertise should make decisions, and ensure full participation by all members of the group; e) all processes should be documented and open to inspection.	(106)	High confidence	Context: WHO Explanation: Minor concerns regarding adequacy of data (data comes from one (non-systematic) review of systematic reviews).
Surveys and focus groups were used. Also, health workers were interviewed so the health facilities' dynamics could be understood. Specific issues were analysed by means of case studies.	(88)	Moderate confidence	Context: Zimbabwe Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one systematic

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			review).
PARTICIPATION MODEL			
The community-based participatory research (CBPR) approach enables the emergence of trustful relations, which are favourable to comprehensive participation. Other favourable instruments were: well-designed surveys, forums, and the recourse to photo and voice recordings. Engagement is successful whenever actors and tribal representatives have the opportunity to engage in all phases of the process. Difficulties that may arise during the process include the design of research tools without full involvement of the community, the inability to understand the community's needs, and the incapacity to motivate participants. Studies that have a poor methodological design can compromise the level of community participation. On the other hand, well-designed methods lead to comprehensive engagement, including the involvement of even "hard to reach" groups. Tools that facilitate large participation include surveys, forums, photos, and voice recording. Post-intervention sustainability can be achieved through the involvement of local institutions such as faith networks, park authorities, and tribal agencies. In this sense, the CBPR experience outlines that initiatives should focus on marginalized or disadvantaged groups. The use of the community-based participatory research aims precisely at coping with power imbalances. For so doing, it is crucial that the right people be selected for the process, including careful consideration for the ethnic composition of the participating group. It is important to seek means to keep the community motivated during the process. Positive outcomes of this approach include: empowerment of community members, improved social networking, and provision of self-efficacy for participants. Barriers to comprehensive engagements include: power struggles between stakeholders, lack of funding and infrastructure, uneven receptiveness from the community, lack of goal-sharing among stakeholders, and community mobility. On the other hand, facilitators include: partner input in intervention design, shared learning between academic and community partners, and bridging people on research teams. Post-intervention sustainability of processes were facilitated by their engagement with faith networks, local authorities, and tribal agencies.	(39)	High confidence	Context: Africa, Bangladesh, China, India and Iran Explanation: Minor concerns regarding adequacy of data (data comes mainly from one systematic review adn there is no specific data extracted that could build this finding for each country in Africa as well as for Bangladesh, China, India and Iran).
Regarding recruitment strategies for both Consultation and Participation Models, it is important to observe the three profiles of social representativeness: citizens ('pure'/naïve public) provide democratic accountability and receive information from sponsors of health technology development, assessment and policy/decision-making organisations as subjects of education and empowerment strategies; consumers (affected public) provide subjects for knowledge exchange and give information to sponsors and are, therefore, educating/enabling experts to reconsider and enlarge their views with first-hand knowledge about life under specific conditions; advocates (partisan public) provide strategic input as to potential competitors, barriers and enablers to specific policy goals, engaging in information exchange with sponsors about the landscape of potential arguments raised by such expert consumers and/or technical experts. Furthermore, despite recruitment strategy (purposive sampling, (non-)stratified random sampling (electoral roll, random digit dialling, commercial database of registered telephone numbers, national polling institute), professional and/or	(49,104,40,15,61)	High confidence	Context: Australia Explanation: Minor concerns regarding adequacy of data (data comes mainly from two systematic reviews).

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market research sampling, newspaper advertisement, word-of-mouth/advertising through networks and/or community organisations (to reach specific disadvantaged and underserved populations, government departments or existing citizens' council), it is important to: a) stratify variables (age and sex (all studies) geographic area (one); race/ ethnicity and education, at least one of employment status, housing tenure, religion and occupation, socioeconomic status, income, social class, car access, health parameters, children and language) to avoid bias and skewed sampling; b) consider duration and timing; c) consider honorariums. The aim is to reflect on transferability of findings to specific populations, such as people from rural or remote areas and/or specific language speakers.			
Citizens' juries and similar methods (such as community juries, consensus conferences, deliberative polling, deliberative public participation meetings, town hall meetings, structured decision-making workshops, deliberative mapping, and deliberative forums) are the most prevalent method for sufficiently diverse and meaningful social engagement so that engaged Australian citizens are exposed to a broad range of public experience and perspectives. Citizens' juries and similar methods constitute useful cost-effective tools that are small enough to allow effective and adequately informed deliberation when compared to other larger deliberative exercises (such as planning cells and consensus conferences). It is important to observe duration and timing of meetings (if alternate and/or consecutive days) to allow sufficient time to explore issues and still deliver representative outcomes of the views presented within the decision-making process. Citizens' juries can be facilitated or not, depending on previously agreed methodology of social engagement sponsor organisations. Therefore, citizens' jury's discussion and/or deliberation meetings can be led by jury members themselves and/or a trained/experienced facilitator. Facilitator has a role in: drafting a proposal for common ground, being neutral in content but active in process, ensuring discussion stayed on-topic, assisting question formulation and reaching for consensus; but, in most cases, it remains undefined, turning deliberation into ineffective social engagement processes. Therefore, it is important to design structured elements to stimulate and guide discussion (such as small group work, scenarios or hypotheticals, scoring methods, priority setting, workbooks, dialogue guide, voting, physical model, and a court room format). There are various methods for both data collection (such as video/audio-recording, contemporaneous notes by organisers or participants, workbooks, whiteboard scribing, flip charts, voting, participant diaries, participant hand-held video-recording, questionnaires, interviews) and (quantitative and/or qualitative) analysis of proceedings (written by researchers based on participants' recommendations, jurors alone, facilitator assistance, researchers in consultation with participants) to produce meaningful, unbiased and representative recommendations from deliberation (such as consensus; consensus with minority opinion; voting; no decision choice dominated). It is important that sponsor organisations are flexible and open to adapt the citizens' jury to instrumental aims to avoid untenable methods that may impose considerable losses to the social engagement process. Independent oversight by a steering committee has helped solve strict adherence to and, in particular, legal regulation of a method, through patent or trademark that could be	(40,15)	High confidence	Context: Australia Explanation: Minor concerns regarding adequacy of data (data comes mainly from two systematic reviews).

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counterproductive for knowledge production since it is through testing and adapting methodologies that new ideas are developed and the understanding expands on certain issues during deliberation.			
Citizens' juries were used, which are useful tools for engaging the public. Different recruitment strategies were used, such as newspaper advertisement, stratified random sample, word-of-mouth, and others. Juries lasted from one to five days. Most juries had a facilitator. It was seen that citizens' juries can help empower citizens.	(40)	High confidence	Context: Brazil Explanation: No concerns for all CERQual components.
The Canadian experience has been prolific in experimenting with deliberative strategies such as public deliberative forums, citizens reference panel, citizens juries, expert reference panels, open houses, community-based participatory research as synonymous of participatory action research and action research, since the goal of deliberation is to provide a mechanism for the voices of ordinary citizens to be incorporated in collective decision-making. • **Planning of the participatory approach is important to graphically map all main aspects of the social engagement process and their relationships to the intended outcomes. In this sense, there are three factors for effectiveness: a) context (there needs to be a policy coalition supportive of social involvement, legitimacy, credibility and power to be involved in collective health care decisions); b) intervention (recruitment strategies must select legitimate groups and perspectives relevant to the intended technology and where it will be implemented; preparation must be supportive of social representation and credible expertise; participation of both citizens/consumers qua patients (and families/carers/legal representatives) and health professionals and decision-makers must support credible 'rational' arguments, legitimate 'collective speech' strategies, power through strategic alliances and productive deliberation; moderation of all participants should aim levelling power differences, legitimising marginal voices into productive deliberation; consultation of legitimate voices speaking on behalf of wider constituencies); c) outcomes (productive deliberations comes from mutual influence and agreement about health technologies improvement priorities). In this sense, HTA sponsors would benefit from clearly distinguishing between patient and public input in terms of representation and agency, as well as between health professionals from health services and/or the industry, and advocates from patient organisations and/or the industry. In this sense, it is also important to consider local legislation/regulation regarding reimbursement of expenses (accommodation needs of health consumers, such as financial, geographical and physical) and/or payment of salary/honorariums during the planning/design phase of the participatory approach. The Canadian experience outlines that such administrative, financial and political constraints shape both design and implementation of many community engagement strategies and may constitute barriers in real-world settings.** • **Recruitment is essential, as approaches that focus in engagement with the general public tend to involve random selection, often with an emphasis on ensuring approximate propositional representation of demographic variables relative to the population or of marginalised voices. In this sense, it is interesting to have a database of potential**	(53,49,28,65,40,38,73,74,66,29, 101,69,60, 39,55,67,56)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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participants and to adequately measure representativeness, as tensions among those who favour the broadest, most diverse and inclusive process possible and those who are more interested in getting the 'right people' or 'key players' involved must be solved during the design phase. The most common recruitment strategies for stratified random sampling are: electoral roll, random digit dialling, commercial database of registered telephone numbers and national polling institute. It is also usual for recruitment to be performed by a market research company, via newspaper advertisements, word-of-mouth, advertising through networks (youth, aged, caregiver or marginalised population groups), or via community organisations, government departments or existing citizens' council. • **The actual design of public deliberations — that can vary from a single meeting held in an evening or over a weekend to multiple meetings held over several weeks or even a year or more. Nevertheless, it is important to notice that time frame and number of meetings are often constrained by both the available budget and the complexity of the topic; costs escalate for multiple meetings, especially if participants are recruited across a large geographical region. It is also important to avoid marginalising lay perspectives; therefore, many deliberative forums have experts as key witnesses or information sources, but prohibit them from actually participating in deliberation. In such designs, the Canadian experience recommends care to prevent one expert or stakeholder from monopolising the attention of the forum. Strategies include strictly enforcing speaking times and limiting the amount of other interactions between experts and lay participants. Other roles that facilitators can perform are: drafting a proposal for common ground; being neutral in content but active in process; ensuring discussion stays on-topic; assisting question formulation and reaching for consensus. It is of upmost importance that facilitators be consultants who specialise in this kind of work, academics familiar with the subject matter, or members or government department or other institution that is hosting the public deliberation. However, the Canadian experience also advises that facilitators should NOT have a vested interest in the outcome of the discussion, as moderation (with the public and/or professionals) should level power differences, legitimise marginal voices, and enable productive deliberation. Other strategies deployed by the Canadian experience are: hiring an expert in communication as lead moderator to assist with formal training in health care to focus on effective group processes, paying close attention to the setting and enforcing ground rules, supporting a relaxed atmosphere conducive to deliberation and compromise, and asking for frequent clarifications when technical language was used — all such strategies are used to minimize power differences, by actively seeking public members' opinions and dissenting voices during discussions to counteract professionals 'lecturing' public members about specific health behaviours, or by using seating plans (i.e. not letting lead physicians sit with CEOs and seating public members in pairs). Regarding expert witness/testimony, participants should engage with moderators and challenge the evidence, after reading workbook with balanced relevant information.** • **Still regarding the design, it is important to have independent-nonparticipant observers with the aim of developing structured observation charts to collect data describing the**			

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deliberation content, the types of arguments used, and the participants' interactions — field notes should be done to record informal interactions that were not captured on video. Furthermore, structured debriefing sessions with the observers and moderators should be held immediately after each meeting, so that key interactive moments can be flagged, and all observations linked to the video-transcript (full verbatim) using time codes to allow later validation against the original video-recording. The idea is to identify varying degrees of public influence — among the different sites, over time, and across topic areas — to identify the components of the interventions that could help explain these variations. • **It is important to synthesise results, as participants themselves take part in developing a report on the proceedings. Nevertheless, writing reports is a technical skill and requires appropriate organisational support; therefore, specialists are usually needed. When a facilitator writes a report of the main findings, or a researcher uses notes or transcripts from the deliberation to create a synthesis of the main conclusions, both options remove the power of constituting the results from the forum participants and give someone else the power to interpret the content of the deliberations. Therefore, skilful group facilitation should be conducted in such a way that conclusions are an explicit product of deliberation, rather than implicitly inferred after the fact. In this sense, the concluding period of a deliberation can be devoted to a facilitated discussion that summarizes the group's deliberations.**			
As a participation method, citizens' juries that, as with legal juries, are based on the idea that 'once a small sample of the population has heard the evidence, its subsequent deliberations can fairly represent the conscience and intelligence of the general public'. Citizens' juries are small enough to allow effective deliberation, relatively inexpensive compared to the larger deliberative exercises of planning cells and consensus conferences, and they are sufficiently diverse that citizens engaged are exposed to a broad range of public experience and perspectives. Citizens' juries may consist of 12–16 individuals recruited to be broadly representative of their community, and are typically charged with addressing complex questions. Regarding duration and timing, jurors usually meet over a 1- to 5- (consecutive or not) days period during which they hear from a variety of expert 'witnesses', who present a range of perspectives on a particular issue, engage in deliberations among themselves, and, ultimately, come up with a 'common ground' set of findings. Jurors should have equal opportunity to participate in the process and express their views, become actively engaged in debates; recall small details about information presented to them over the jury's time period and develop a sense of community, shifting their views from more self-interested ones to solidaristic ones. In this sense, although jury length did not appear to impact on recruitment bias, longer juries were balanced in terms of the selection criteria, given measures were taken to support recruitment of hard-to-engage groups, and allowed participants greater control over the ensuing report, providing them with the opportunity to engage with different forms of evidence. Therefore, moderation should be structured to stimulate and guide discussion (such as small group work; scenarios or hypotheticals, scoring methods, priority setting, workbooks, dialogue guide, voting, physical model, and court room format).	(53,49,28,65,40,38,73,74,66,60)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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In this sense, the Canadian experience identified that a facilitator is to always start by asking local/national patients groups 'what do they want' (via surveys and/or other consultation methods) during the design phase. Citizens' juries usually start the first session/day by nurturing a climate conductive for citizen participation with welcomes and introductions, followed by a series of 'ice-breaker' exercises intended to give jurors an opportunity to develop a comfort level working together. The first session/day ended with presentations that: a) discussed the need to make tough but fair decisions regarding which health technologies to fund publicly; b) defined HTA and its role in informing such decisions (i.e. what HTA is and why it is done); c) introduced the main HTA-producing organizations in the country; and d) outlined the steps involved in a citizens jury (i.e. what jurors could expect over the next days). Open access, lay language and updated background materials should be circulated in advance of each meeting, and must include: HTA evidence summaries and draft recommendations (for one or various technologies under evaluation), relevant review articles and newspaper clippings, and a workbook, which summarises balanced key attributes of each technology and the discussion questions. Each meeting/session agenda should include an overview of each discussion topic followed by a Q&A session and a combination of large (externally facilitated) and small (self-facilitated) group discussions with reporting back and thematic summarising sessions. The Canadian experience further outlines that adapting citizens' juries to instrumental aims constitutes a facilitator for implementation of citizens' juries, although particular care and attention should be paid to recruitment methods, independent oversight by a steering committee, jury duration, moderation and respect for the participant volunteer. The second session/day usually starts with presentations from expert witnesses and, at the end of each presentation, jurors should have an opportunity to 'interrogate' witnesses during a question and answer period. Engagement with first scenario-based priority-setting exercise aims to identify criteria, in no particular order, that might be used to guide priority-setting for HTA (jurors can be presented with one to various mini-technology scenarios taken from actual HTA requests submitted by regional and provincial policy-makers within the past year — each scenario can comprise one paragraph describing the technology and indications for its use, the number of individuals anticipated to benefit and, where possible, its estimated unit or per case cos). The level of information provided should reflect that typically received by those involved in setting HTA priorities for the local level. After independently rating the importance of each technology on a scale of 1-5, jurors should meet in small groups to share and explain their choices and compile a list of criteria based on their rationales or reasons. Then, they should reconvene to deliberate over and agree upon which criteria to include in an initial draft set. Sometimes, it may be interesting to request for participants to prepare questions for deliberation days. The third session/day can be dedicated to 'testing' out and subsequently refining the draft set of criteria to create a ranked list (jurors can engage with a second scenario-based exercise comprising two in-depth case studies derived from local technology issues – for each technology, jurors should hear from and ask questions to: a patient with the condition, a health-care provider who treats the condition, a policy-maker involved in determining the			

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reimbursement status of new technologies and the manufacturer of the technology. The Canadian experience outlines that it is important to familiarize expert witnesses with the jury process and ensure presentations capture a broad range of perspectives, mock sessions (which can be overseen by moderators from more experienced HTA organisations such as the UK's NICE — that can be held prior to the actual session). Following presentations from expert witnesses, each juror is asked to decide which of the technologies should receive higher priority for assessment and explain his ⁄ her decision. Jurors then split into four small groups to: a) discuss how they had applied the initial draft set of criteria to their own decision-making process; b) deliberate over any necessary modifications to the criteria; and c) rate each revised criterion as 'extremely important', 'quite important', 'important' or 'not important'; jury then reconvened to review the findings from each group and establish, through consensus, a final ranked set of criteria (achieved by resolving discrepancies in terminology across groups and weighting each criterion, multiplying the frequency with which it appeared on the groups' lists by the magnitude of the importance 'score' it received – criteria is then to be ordered according to the sum of their weighted scores [highest sum (most important) to lowest sum (least important)] to generate a ranked list, which is to be subsequently finalised by the jury). Collection of data can be audio-recorded, organisers or participants can make contemporaneous notes, workbooks; video-recording, whiteboard scribing, flip charts, voting,; participant diaries, participant hand-held video-recording, (self-administered) questionnaires, (in-person and/or telephone and/or online) interviews, and/or other methods ensemble and/or individually. Data analysis can be both quantitative and/or qualitative (such as content analysis, close and repeated reading, discourse analysis, coding). Output recommendations can be produced via methods such as consensus, consensus with minority opinion, voting, no decision choice dominated – it is essential, however, to ensure that citizens/consumers' qua patients' (representatives) and advocates' input is clearly outlined before and within dissemination materials to avoid creating false expectations that diminishes adherence to the social engagement initiative. As aforementioned, jury reports can be written by: researchers based on participants' recommendations, jurors alone, facilitator assistance, and/or researchers in consultation with participants. Dissemination of jury findings can be made via academic literature, (social) media coverage, direct presentation to decision-makers, direct community engagement, and/or planning meetings. Moreover, the Canadian experience enumerates a series of facilitators for the implementation of citizens' juries, namely: a) it would be interesting to conduct more than one jury with the same jurors and several juries with different jurors respectively; b) promoting and providing training and educational support for policy/decision-makers and health consumers representatives in lay language on: health issues, health policies and programs; information on the technology being reviewed; information on the scientific process; information on the research process; information on planning and evaluating; information on procedures for meetings; information on communication and networking skills; development and maintenance of a web page for information dissemination; organisation and facilitation of educational workshops; evaluation of program and process			

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effectiveness; recognition and support of formal health consumer stakeholder involvement process; c) during post-data collection, it is interesting to allow jurors to reflect on their individual preferences prior to the jury and support their feedback on whether they still agree with its content and provide the opportunity for any additional comments to output recommendations; and d) it is important to provide and support access to experts for advice throughout the jury process to facilitate jurors engagement with evidence and educational materials. **NB. We highlight that we have classified citizens' reference panel, 'open houses' and mandate as citizens' juries due to the similarity amongst their design and implementation approaches and procedures described in the literature reviewed. All such methods aim to provide opportunities for 'two-way exchange' between policy/decision-makers, health professionals, advocates and society at large in an informal, non-confrontational manner, avoiding the emotional and divisive nature of the 'us' versus 'them' atmosphere of public deliberation meetings.**			
Deliberative public participation is a method whereby controlled participant sampling and recruitment methodology (20-25 participants selected from each community) is deployed to gather social actors with an inte[40]rest in health technology assessment in a 1-day (6h), face-to-face meeting, consisting of plenary (held at the beginning and end of the day) and small group (held between the plenaries) sessions that will provide the sponsoring regional health authority with public input on an issue of importance with provision of an external facilitation of the participatory method. Participants are provided with standardised information materials tailored to the local issue in advance of the meeting, and there is a combination of structured and unstructured aggregation of input. There is a requirement for each organisation to clearly communicate to participants the purpose and intended use of the public involvement process and how their input will be used by the organisation. Evaluation of participants input is based on the completion of questionnaires prior to (baseline), immediately following (post) and 3-4 months after the 1-day consultation meeting (follow-up). Only (itemised) data relevant to method's procedural elements are to be reported. Baseline evaluations should focus on assessing clarity of communication about the purpose of the consultation and about the background materials provided in advance of the meeting; whereas, post-meeting and follow-up surveys should focus on specific procedural elements of the meeting and on meeting follow-up. Prior to the consultation meeting, decision-makers' evaluation encompasses the completion of a brief questionnaire meant to gather their perspectives on: a) the amount of planning time required for the consultation meeting; b) expectations for the meeting and the potential for the deliberative method to foster a different kind of discussion and citizen input than typically obtained; c) criteria they would use to judge if the meeting was successful; and d) least and most satisfying aspects of planning for the meeting. Post-consultation decision-maker evaluations should be administered through surveys and debriefing meetings with the HTA organisation decision makers involved in the project, research team members and the consultation facilitators. E-mail exchanges initiated by decision makers providing feedback on the consultation should	(53,49,28,65,40,73,74,38,66,29, 42,101,69, 60,39,55,67,56)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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also be reviewed. The Canadian experience also outlined a few facilitators on this type of participation method, namely: a) that the method clearly performed better under some circumstances than others and that the different contexts within which this type of method was implemented made a difference — close matching of method to context are, alongside careful implementation, critical elements; b) deliberative public participation method appears better suited to certain types of issues such as: b.1) clearly defined issues for which there are at least a few acceptable decision options; b.2) issues for which there are tangible links between the consultation being sought and the decision that is being taken; c) leadership and commitment at all levels of the organisation clearly plays a crucial role in facilitating successful implementation (e.g. in following through with participants long after the consultation day is over and in the clarity of the communication about how the public input was considered and used) — commitment can be easily undermined by competing priorities for senior managers and board members, by inadequate resources to fully implement the procedural elements or by the lack of receptivity to new approaches at the staff level; and d) exposure to this method through participation in a collaborative research study of this kind can exert direct effects, at least in the short term, on organisational thinking and practice regarding public involvement design and implementation.			
It is important to consider that participation comprises three domains: policy domain (measures to involve the public), organisational domain (the agency's design of participatory processes), and research domain (methodological tools). The aim is to make individuals able to propose, discuss, and test assumptions about technologies. Constraints to participation include: resistance from HTA agencies; scarce resources; claims that it is too early to seek participation; too late involvement in the HTA process; too high expectations from the public; concerns about the technical contents of HTA; and unwillingness to engage patients and representatives. The transparency from the HTA agency was a decisive facilitator.	(75,49,52,67)	High confidence	Context: Denmark Explanation: No concerns for all CERQual components.
Analytic Hierarchy Process (AHP) workshops are conducted, allowing patients to express preferences and values. In these workshops, patients and professionals compare endpoints by means of a quantitative scale, subsequently discussing these preferences and values. A difficulty found in this approach is the small number of participants, which require a careful selection of participants, as well as a careful selection of endpoints to be assessed. Furthermore, the AHP method should only be used when quantification is possible. On the other hand, AHP enables to identify instances in which treatments deviate from patients' preferences, to prioritize HTA topics, and identify the most relevant endpoints.	(54)	Moderate confidence	Context: Germany Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one primary (case) study that comprises a systematic review and a mixed-methods study).
HTAi outlines two frameworks to help HTA organisations/sponsors/agencies choose the best social engagement model/method for the assessment of different types of health technologies by: a) Rowe and Frewer (2005) typology of social engagement based on the direction of flow of information between participants and the 'sponsor' (in this case, the HTA organisation): communication (typically provision of information on a website), consultation (focus groups and discussion documents), and participation (only a small proportion of agencies undertook participatory approaches — particularly deliberative methods such as consensus panels and citizens' juries — but there is growing interest in these methods); b)	(19)	High confidence	Context: HTAi Explanation: Moderate concerns (data comes mainly from one (non-systematic review) primary study).

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the International Association for Public Participation (IAP2) (1999) 'Spectrum of Public Engagement' — a framework that outlines the different types of engagement (inform, consult, involve, collaborate, empower) that organisations can undertake as a continuum of levels of social engagement where the most appropriate engagement format is selected depending on the topic (limitation: lack of guidance given to direct this selection). According to the HTAi experience with frameworks for choosing a social engagement method, there are four main drivers that influence the choice of social engagement model/methods undertaken by HTA organisations: a) perceived complexity (driven by the content of the HTA itself such as the characteristics of the technology under review, the research question, and the type, quantity and quality of the evidence available — e. g.: medical tests (screening, diagnostic tests, co-dependent technologies) are often considered complex due to the type of evidence available, the quality of this evidence, and the subsequent assumptions that need to be made when transforming this evidence for use in an economic model assessing final health outcomes) and uncertainty (about evidence of safety and efficacy, therefore, as complex decisions often need to be made regardless of the level of evidentiary certainty, social engagement activities need to facilitate understanding); b) perceived impact of (sensitivity of) a topic/decision (external to the organisation) on (the interests of) stakeholders (depends on the characteristics of both the disease and the technology both to the individual and society); c) time (two to three weeks need to be added to completion time each time a decision making committee meets) and (financial and knowledge) resources available to the HTA organisation (internal factors) are key to substantially alter the trade-off between engagement and timeliness, as most HTA organisations also undertake social engagement activities themselves, rather than engaging expert external groups, so the type of engagement will therefore be dictated by skills, knowledge and preferences of the HTA organisation; d) existent organisational culture, structure and processes of the HTA organisation (transparency and opportunity for public involvement in governance — internal factors) are key to choose a social engagement model/method as a way of promoting greater trust and confidence in the system and ultimately legitimacy in the decision. The HTAi experience has identified a couple of barriers to the implementation of frameworks that help choose a social engagement model/method for specific types of health technologies, such as: a) frameworks do not suggest a hierarchy of effectiveness of engagement methods; indeed research on the comparative effectiveness of the different types of engagement and the use in different stakeholders is lacking; b) deliberative methods are effective in increasing knowledge; however community deliberation and citizens' panel techniques may be more appropriate for more complex topics; c) it may be that society is happy not to be involved in decision making, or that they have an unexpected preference regarding the most appropriate mode of engagement. Facilitators have also been identified by the HTAi experience, namely that: a) HTA organisations should also take note of studies that are focused on asking what society wants in relation to engagement to inform discussions as to whether and how engagement should take place within an HTA sponsor — in the sense of citizen science approaches; and b) novel quantitative methods to incorporating the values of			

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citizens/consumers qua patients (families, carers, legal representatives) and advocates in HTA decision-making (models of value based pricing, multi-criteria decision making (MCDA), discrete choice experiments) could focus social engagement activities on developing relative weights for criteria around the complexity and impact of an HTA and could potentially lead to more transparent and systematic public engagement processes, as well as capture many of the benefits of directly incorporating preferences and social values into decision-making whilst avoiding the time delay and cost associated with undertaking additional social engagement.			
Mini-publics and health parliaments were organized, with people supposed to represent the public in general. In this way, three types of questions can be addressed: levels of funding, types of services or reimbursement to be offered, and eligibility of patients or groups. Barriers included: the limited number of participants, the technical nature of the discussions, the highly controversial nature of the issues discussed, lack of evidence, difficulties to make discussions egalitarian, and concerns with the representativeness of mini-publics. This is why the groups mobilized should be as diverse as possible, making sure that minority groups are included.	(34,86)	High confidence	Context: Israel Explanation: No concerns for all CERQual components.
Citizens' juries are organised via a wide range of recruitment techniques (over 20 techniques) are mobilised, the most frequent ones being: stratified random sampling, electoral roll, random digit dialling, use of commercial database of telephone numbers, and recourse to a national polling institute. Juries took from one to five days. Some juries had facilitators, others did not. In most juries, a final jury report was prepared. Barriers were: administrative, political, and financial constraints; the definition of too narrow standards and procedures for juries' operations; the conduct of processes that undermined the public's confidence, and the adherence to too strict guidelines. Facilitators were: a well-designed recruitment strategy; accurate facilitation, guaranteeing a space for everybody's expression; and the provision of space for participants and facilitators to express their experiential knowledge; and the involvement of participants in early phases. One important facilitator was the adaptation of the juries' features to local characteristics and to the issue at stake.	(40)	High confidence	Context: Italy and New Zealand Explanation: Minor concerns regarding adequacy of data (data comes mainly from one systematic review).
Participation processes are used at the local level, in the context of health technology implementation and monitoring. Health Facility Committees are established in the units providing health care. The goal is to enhance accountability in relation to the public, promoting co-management of resources, continuous dialogue and joint reviews. Outreaching activities aim at promoting health and fostering health-seeking behaviours. The views of the public must be transmitted to health facilities. Barriers to engagement were the hierarchies (social, economic, cultural, geographic, and political) that existed previous to the formation of committees. Previous hierarchies (social, economic, cultural, geographical, and political) emerged as barriers to full participation.	(88)	Moderate confidence	Context: Kenya, Peru and Uganda Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
Direct participation is key in the HTA process as peoples' perspectives could add important dimensions to the evaluation of technologies and clinical interventions, including user-defined viewpoints that may channel the focus on issues that are important for citizens/consumers qua patients (and their families, carers, legal representatives) as well as	(84,49,41,30,36)	High confidence	Context: Netherlands Explanation: No concerns for all CERQual components.

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advocates. As such, it is important that HTA organisations have both open working style and innovative culture. From a methodological perspective, it is essential to collect audio-recordings or note-takings from discussions – audio recordings should be transcribed and/or notes (all anonymised) written up after each meeting so that each local co-ordinator can analyse data to identify key issues. Data synthesis can occur through various ways but it is important to find and categorise broad 'themes' using approaches guided by qualitative research such as thematic analysis, grounded theory, etc. It is also important to follow checklists on reporting qualitative findings, such as COREQ (Consolidated criteria for reporting qualitative research), and checklists for reporting societal engagement with research, such as GRIPP (Guidance for Reporting Involvement of Patients and Public). Key identified facilitators to the implementation of participation methods by the Dutch experience are: a) both lay and professional stakeholders can contribute much experiential knowledge, assisting project development; b) stakeholders, including patients and the public, can assist in designing research, which changes their roles and relationships with researchers; c) engaging stakeholders early in project development in various locations can be a major strength as it assists the identification of issues that are common across various locations and levels, providing 'added value' as it enhances the likelihood of the findings having both local and global (glocal) relevance.			
A participatory budget experiment was used to prioritise financial resources allocation on health care programs. Such method includes focus groups and ranking exercises with three different tools for preference elicitation that have been combined for policy making but which can be used for health technology assessment purposes, especially for budget cutting. Regarding the ranking exercises, the tools deployed for preference elicitation were: a) willingness to assign (WTAS); b) cost priority ranking (CPR); c) willingness to pay taxes. Regarding the focus group method, the experiment used participatory and group allocation mechanisms so that participants could engage in discussion as a group, on the reasons for the collective decisions. The Spanish experience also identified a series of barriers regarding the implementation of the participatory budget experiment, namely that: a) extra effort was required to engage participants and aid responses; b) participants presented limited experience as decision-makers, given not all groups were equally dynamic and participatory, and general weakness of public participation mechanism in collective decision making lies in dealing with individual's reluctance to participate which over-represents the preferences of certain population groups.	(76)	Moderate confidence	Context: Spain Explanation: Serious concerns regarding adequacy of data (data comes mainly from one primary (case) study).
Stakeholder conferences have been held with the presence of county councils, local politicians, and lay participants. The Swedish health system was the main topic of discussions. In Sweden, such initiatives can capitalize on the population's strong community involvement, as most people belong to an organization or cooperative. In addition, participation is facilitated by the high educational level. However, most participants were old people, causing an underrepresentation of young people. Follow-up meetings were organized by some country councils. Eventually, some councils proved more active than others in promoting further actions and measures for public participation.	(75,94)	High confidence	Context: Sweden Explanation: Minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies).

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Participation processes are used, at the national level, for health technology policy and decision-making. A two-day civic groups forum was organised. Initially, participants were provided with divergent opinions given by experts. This was followed by group discussion. Conclusions can be reached by either deliberative methods or polling methods. Barriers included a sense a mistrust and division among participants. Facilitators included success in disseminating a sense of communitarian participation in the group, and the notion that participation has a concrete impact in health policies.	(31)	Moderate confidence	Context: Taiwan Explanation: Serious concerns regarding adequacy of data (data comes mainly from one primary (case) study).
Direct participation of citizens'/consumers' qua patients' (families'/carers'/legal representatives') and advocates' representatives in the HTA process provides social perspectives that could add important dimensions to the evaluation of technologies, clinical interventions and health programs, including user-defined viewpoints may channel the focus on issues that are important for health systems users. In this sense, the UK experience has been prolific in both experimenting and implementing direct participation approaches to social engagement in HTA processes. All NICE's and SMC's participation methods involves certain types of barriers to their implementation, such as: a) recruitment of participants is a sensitive and time-consuming issue due to challenges in identifying appropriate consumers, collaboration with consumer organizations may also be difficult (groups who have very strongly held beliefs could be less willing to be constrained by research evidence), and understanding their role and issues addressed is not always easy for lay people; b) speed of discussions; c) unfamiliarity with the HTA process; d) use of technical language and acronyms; e) some tasks may be too technically demanding for users; f) participation in evaluation activities requires some specific abilities or skills (work in a multidisciplinary team); g) unfamiliarity of lay people with research needs; h) physicians', HTA implementers' and researchers' unfamiliarity with health technologies' users organisations and their ways of working; i) time and additional resources required for involving social representatives. A series of facilitators have also been listed, such as: a) focused invitations (i.e., inviting people who have experience related to the topic); b) citizens'/consumers' qua patients' (families'/carers'/legal representatives') and advocates' mentoring, training, support, and the presence of an induction day; c) well-defined outcome-focused presentation; d) appropriate setting and timing of consultation activities (easy walking distance and convenient day of the week); e) open working style and innovative culture in HTA organisations. • **Primary Care Groups (PCGs — introduced in 1998) undertook a number of initiatives: held a citizens' jury to consider the role of GPs in health care rationing; developed a citizen's panel; held a public conference; and amended the way its board operated in order to make proceedings more accessible to the public. PCGs continue the tradition of appointing non-NHS personnel to health authorities to function as scrutineers for the public and therefore reinforce the accountability of the NHS (a lay 'voice' that contributes to PCG proceedings and, if necessary, can advocate the need for public consultation or participation. Nevertheless, barriers are inherent in incorporating social participation in decision-making, such as: a) resources (time, knowledge, skills); b) attitude of PCG board members to the**	(49,34,91,40,94,95,93,60,46,9, 39,67,30)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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idea of public consultation and participation (discomfort with the idea of social participation or the desire to maintain a firm control over the process is evident for GPs — consequence of the relative immaturity of the process in the health service).			
Mini-Publics constitute an important form of (direct) social participation that straddles the divide between public deliberative system and individual survey response, as they can take different forms: citizens' juries, citizen panels, consumer forums or deliberative polls. NICE's Citizens Council work as mini-publics (closely integrated into the decision-making system). Israeli Health Parliament organised six mini-publics (established by officials from the Ministry of Health, researchers from Tel Aviv University and members of the Zippori Center for Community Education) held in six regional groups in community centres, where participants were asked about their views on issues of equity and rationing. Mini-publics comprise a group of lay persons selected to be descriptively 'representative' in some sense of a wider public and asked to deliberate about a policy issue and provide an opinion — whereas citizens' juries aim for consensus, and deliberative polls prompt individual responses to be aggregated. Like surveys, their Consultation function is typically to provide policy makers with information about public preferences and attitudes. However, unlike conventional surveys, mini-publics ask participants to deliberate about a general policy question, often from the point of view of a citizen rather than a patient, and conclude on that question (active Participation). Mini-publics can also occur as ad hoc one-off events. UK Mini-publics have addressed three broad types of questions through social (direct) participation: a) decisions on overall levels of funding; b) decisions of principle on the type of services to be offered or reimbursed, including the principles used in HTAs; c) decisions on the eligibility of different types of citizens/consumers qua patients (families/carers/legal representatives) and advocates or groups (may also add questions of monitoring and evaluation). Most visible forms of priority setting concern which medicines or procedures to provide or reimburse within the scope of public coverage — disinvestment raises similar problems compounded by the fact that, where there are established services, individuals and groups will have acquired legitimate expectations in the availability of care; therefore, decisions on services, particularly decisions to reduce or close services, are often controversial and provoke public participation of the contestatory kind. Nevertheless, overall funding opportunities for (direct) social participation on such decisions are typically limited, as there is some form of (direct) social participation in choices when social representatives sit in an official capacity on decision-making bodies, but the number of public members is necessarily limited, and each public member can quickly become an 'institutionalised' expert. The UK experience has also identified a couple of barriers to mini-publics' implementation, namely that: a) given the role of routinized contestation in some priority setting contexts, particularly in Latin America, South Korea and South Africa, it might be advisable to move away from a focus on Habermas-inspired ideals of consensus via mini-publics to look at ideas of radical democracy[108]; and b) there is relatively little empirical evidence as to how it affects the decisions made, whether it 'improves' decisions against some specified desirable criteria, and few attempts to assess the extent to which it conforms to democratic norms. Furthermore,	(34)	Moderate confidence	Context: UK Explanation: Moderate concerns regading adequacy of data (data comes mainly from one primary (case) study).

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legitimacy and representation are particularly relevant to questions of public participation in priority setting. Therefore, small-scale deliberations such as mini-publics do not necessarily satisfy conditions of what constitutes legitimate representation as the representatives in these forums have neither been elected nor selected through democratic processes to the non-participants who may be affected by the outcomes of deliberative processes. Such lack of legitimacy and representation raises complex questions about whether deliberative processes can, or should, be used as instruments to inform policy and decision-making. In this sense, since those who are politically active through parties and interest groups (patient group representatives) are socially unrepresentative of the population at large — this is partly why mini-publics have become popular in some discussions around social participation in health care decision-making. Mini-publics can be seen as a way of rectifying the imbalance of representation brought about through the selection processes inherent in electoral politics, although there are more important caveats on whether this amounts to legitimate representation.			
Citizens' juries are a useful tool for engaging citizens in health policy decision-making that are small enough to permit effective deliberation, relatively inexpensive compared to the larger deliberative exercises of planning cells and consensus conferences, and sufficiently diverse that the citizens engaged are exposed to a broad range of social experience and perspectives. Citizens' juries bring together a group of people to deliberate over a specific issue. Specifically, they are given information and invited to 'cross-examine' witnesses during the process. There are various methods for recruitment, such as: a) most common (stratified random sampling, electoral roll, random digit dialling, commercial database of registered telephone numbers, national polling institute); b) less common (non-stratified random sampling through electoral roll, random digit dialling or survey response); c) recruitment by a market research company; d) using professional recruiter who directly recruited individuals at public sites; e) newspaper advertisements; f) word-of-mouth/advertising through networks (i.e. youth, aged, caregiver or marginalised population groups); g) via community organisations, government departments or existing citizens' council. It is also very important to devote some time for designing the activity, planning its objectives and ensuring that participants' profile are stratified according to certain variables (e.g., age, sex, geographic area, race/ ethnicity, education, employment status, housing tenure, religion, occupation, socioeconomic status, income, social class, car access, health parameters, children and language) — bias usually appear for age, gender, education and income. It is also important to plan duration and timing as citizens' juries mostly last for 1-2 days (usually on a weekend); considerably fewer last for 4-5 days (recommended), and the longest have lasted over 5 consecutive weekdays (with all but two participants unemployed or retired). The main barrier regarding duration has been having insufficient time to explore the issues (providing the opportunity to engage with different forms of evidence and discussion). Nevertheless, brief daylong juries still delivered outcomes, as modified citizens' juries (as one developed to deliberate around e-Health) can last for one day only. Moderation is another key feature that must be planned as its roles are: a) drafting a proposal for common ground; being neutral in	(34,40,93)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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content but active in process; b) ensuring discussion stayed on-topic; c) assisting question formulation and reaching for consensus. There are other structured elements that moderators can use to stimulate and guide discussion, such as small group work, scenarios or hypotheticals, scoring methods, priority setting, workbooks, dialogue guide, voting, physical model, and a courtroom format. The UK experience further outlines the importance of deploying expert testimonies and expert witnesses so that participants can engage with presenters and challenge the(ir) evidence. Participants should be sent balanced and relevant introductory materials about the issue under deliberation, the citizens' jury process, and a programme for the day, the aims of the jury and a set of questions to be debated — these can cover perceptions and attitudes, such as priorities, besides identified barriers and ways of overcoming them, locally. Reimbursement and honorariums, as well as lunch and refreshments must be considered with care. During the citizens' jury's activities, it is important to design the first session as an activity to increase participants' knowledge about the issue of interest and its current and potential development (videos and 'witnesses' can deliver key messages from their perspectives), as well as the opinion of specialists with opposing perspectives, allowing jurors with the opportunity to cross examine these perspectives. During the second session, the jury should debate the pre-set questions in the presence of a moderator so that they can be asked to make specific decisions regarding the questions put to them and identify key points, which could be agreed upon before moving on to other questions — dissenting views are encouraged to be discussed and debated. All such debates and discussions should be recorded and notes are to be taken by a (trained) observer and one of the jurors, so that recordings and notes can then be used to produce a comprehensive report, which is to be sent to jurors for verification as an accurate record — jurors should be given the opportunity to make changes to this report. Jurors are also given an evaluation form to complete and asked to rate various aspects of the jury using different types of tools, such as a five-point Likert scale. Data collection of proceedings can be audio-recorded or come as contemporaneous notes by organisers or participants, workbooks, video recording, whiteboard scribing, flip charts, voting, participant diaries, participant hand-held video recording, questionnaires, and interviews. Data analysis (qualitative) can involve: content analysis, close and repeated reading, discourse analysis, and coding. Recommendations can come from consensus, consensus with minority opinion, voting, and no decision choice dominated. Jury reports can be written by researchers based on participants' recommendations, by jurors alone, with facilitator assistance, and/or by researchers in consultation with participants. Dissemination of recommendations can occur via media coverage, direct presentation to decision-makers, direct community engagement, planning meetings. The UK experience has identified administrative, financial and political barriers that have shaped design and implementation of many social engagement strategies in real-world settings, such as citizens' juries. Another says that purity about the nature of the ideal deliberative process — such that the methods are untenable within the constraints of the decision-making process — may impose a considerable loss to community engagement. Furthermore, strict adherence to and, in particular, legal regulation of a			

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methodology, through patent or trademark, could be counterproductive for knowledge production since it is through testing and adapting methodologies that new ideas are developed and our understanding expands. Challenges have been associated with using broad, open-ended questions. If the debate is facilitated in a more adversarial style, or if the jurors are forced to make resource-constrained choices, it may generate more conflicting views, which jurors can then have to work through and reconcile. In this sense, providing jurors with information in advance of, and in the early part of the meeting, could be seen as potentially introducing bias to the proceedings and facilitating the regurgitation of the experts' views in the encounter — nevertheless, this approach is commonly used, the information provided to the jurors is to be unbiased, and there should be transparency about what is known and not known about the issue of interest under deliberation. The UK experience has also identified a few key facilitators to the implementation of citizens' juries. First, it is important to adapt citizens' juries to instrumental aims — particular care and attention should be paid to recruitment methods, independent oversight by a steering committee, jury duration, moderation and respect for the participant volunteer. Juror selection may be dependent of formal requirement for 'citizenship' of the country in which the jury will occur — importance of addressing juror-policy/decision-maker interactions (citizens have reported the need for greater 'accountability' by policy/decision-makers who support deliberative forums so that citizens can feel that their input is wanted and is going to be needed). Other features observed as critical to implementing successful citizens' juries are: a) recruitment strategy: jurors were recruited purposively to get a broad range of demographic characteristics and to include lay people with some experience of representing a view in a group setting — recruited jurors were able to contribute to the discussion and listen critically to others' views and in this way the recruitment strategy was successful; b) transparency: information given to the jurors was presented and communicated in a clear and accessible manner; the review of literature reflected both the opportunities and the challenges in the implementation of the health technology of interest; during the day, the jurors were given as much time as they wanted to cross-examine the witnesses; c) independence: university researchers who acted as moderators — awareness of the significance of influence on the process and strove to ensure independence (e.g., explain the challenge of moderators' role to the jurors and refrain from giving opinions when asked during the debate and at other times during the day). Finally it is very important to ask jurors to verify whether or not a written report of the jury's events was a true representation of their experience. In this sense, citizens' juries should allow expression of public perspectives, something which is often missing from the rhetoric on this subject — relatively inexpensive (method that could be replicated by decision/policymakers and others wishing to engage with society in this area, not least as a way of building public confidence in health technologies).			
Whether the US experience assumed a 'high-touch' — convening real-world multi-stakeholder advisory groups to discuss research governance; hosting a 'town forum' to obtain input and discuss key issues related to a research topic; convening real-world	(49,45,40,78,80,82,81,77,39,56)	High confidence	Context: USA Explanation: Minor concerns regarding adequacy of data (data

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meetings to rank priorities for research through discussion or card-sorting; organising individual meetings with relevant organisations to discuss research findings and approaches for disseminating information; and/or inviting stakeholders to help recruit from within their community — or a 'high-tech' approach — launching online campaigns to crowdsource topics for research and a virtual advisory group meeting through telepresence (e.g., Google Hangout, GoToMeeting!, WebEx!); using telepresence to conduct a video conference with stakeholders to present and discuss research projects; digital video/audio capturing to web-stream or archive discussions, collaborative notes taken with Google Docs; posting consent forms, questionnaires, research hypotheses on a collaborative website, for example, Google Docs and allowing commenting or even editing by community; and/or inviting stakeholders to join social media campaign (e.g., Thunderclap) — they are usually guided by the Federal and Drug Administration's (FDA) decisions and public deliberations focus on a Habermas2-4-inspired way of making decisions — a process of reasoned exchange in which participants listen to others as well as voice their own opinions (the Participation Model, according to the typology we have developed in this systematic review). The Participation Model, as opposed to the Information and Consultation models, can produce outcomes that are more legitimate by allowing all views to be considered and (potentially) influenced by one another. The US FDA experience has identified a few barriers to both planning and implementing participative methods of deliberation. First, achieving broad participation while ensuring a meaningful exchange in which participants have an equal opportunity to participate is difficult, as formal public representatives in advisory boards may not be sufficient to address the desire for public input into policy decisions not tied to specific drug or device approvals. Second, being vigilant about lobbying of groups that are merely fronts for industry while simultaneously expanding its efforts to recruit representatives from a broader array of legitimate organisations that serve patients and consumers is difficult, as efforts to bring about greater public input can be viewed as mere 'window dressing'. In this sense, the FDA offers training for patients representatives including 'FDA 101 Training', monthly webinars, and an annual workshop for newly recruited patient representatives. The FDA also solicits additional patient representatives if they need someone with particular expertise or know about a possible conflict with one of the existing representatives, as the limited number of participants in these programs raises questions about the extent to which the FDA is hearing all relevant perspectives. Third, arranging a deliberation among a large number of participants is difficult because it is less likely that all participants will make a meaningful contribution to the discussion. In this sense, facilitators to overcome this challenge would be: a) to rotate representatives from different organizations; b) to encourage and help the groups represented at FDA meetings to reach out more effectively to the communities they represent (Friends of Cancer Research hosts a conference every year at which they identify 4 core ideas that are of interest that the FDA could address and form a board that works for 4-8 months, with participation by the FDA, scientists, advocates, industry, and patients, and develops an article for public presentation). The US FDA has also identified a series of facilitators to the implementation of deliberative methods, such as: a) benefit-risk tools that			comes mainly from two primary (case) studies that consistently represented other data expressed in textual wording from other studies).

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help tell a story (What is the problem? What other potential solutions exist? What is the benefit of the proposed solution? What am I worried about? What can I do to mitigate or monitor those concerns? The analysis of the questions and unmet clinical needs are issues on which input from patients and consumers would be particularly fruitful and may be valuable to apply this broadly); b) broadening social participation in decision-making may increase HTA sponsors' attention to heterogeneity and lead to flexibility in analysis (this can be done by early social engagement in the HTA process); c) balancing faster versus complete analysis that also encompasses implementation barriers and facilitators to health technologies can be tackled by legitimate trustworthy social engagement activities, particularly those that foster broad deliberative processes. Canada, the UK and US policy/decision-makers have used methods such as deliberative polling's, citizens' juries, consensus conferences, and town hall meetings to solicit information from the public about values to inform 'planning and resource allocation decisions' for a variety of issues. Therefore, resources should be focused on training on the process of deliberation as well as in the value of regular interaction.			
Regarding Citizens' juries as a Participation method, the US experience outlines its importance as a useful tool for engaging citizens in health policy decision-making because they are: a) small enough to allow effective deliberation; b) relatively inexpensive compared to the larger deliberative exercises of planning cells and consensus conferences; and c) sufficiently diverse that the citizens engaged are exposed to a broad range of public experience and perspectives. Recruitment strategies can be varied, such as: a) the most common are stratified random sampling (electoral roll, random digit dialling, commercial database of registered telephone numbers, national polling institute); b) the less common (non-stratified random sampling through electoral roll, random digit dialling or survey response); c) recruitment by a market research company; d) professional recruiter who directly recruits individuals at public sites; e) newspaper advertisements; f) word-of-mouth/advertising through networks; and g) community organisations, government departments or existing citizens' council. A citizens' jury objective is to be descriptively representative of the community, providing a cross-section of community perspectives, incorporating diverse voices. Therefore, the US experience outlines the importance of stratifying variables such as age, sex, geographic area, race/ethnicity, education, employment status, housing tenure, religion, occupation, socioeconomic status, income, social class, car access, health parameters, children and language. During designing, it is also important to discuss honorariums to avoid bias due to skewed recruitment and/or sample variables stratification. Duration and timing are also essential aspects of planning as most citizens' juries last for 1-2 (consecutive) days (usually over a weekend), and there have been considerably fewer that lasted for 4-5 days as, although longer juries provides participants with the opportunity to engage with different forms of evidence, brief daylong juries still deliver the expected outcomes. Regarding planning moderation, facilitators must be trained, skilled or experienced in the citizens' juries design and should have independence from the HTA sponsoring organisation. The facilitator's roles are: a) drafting a proposal for common ground; b) being neutral in content but active in process; c) ensuring discussion stayed on-	(40,77)	High confidence	Context: USA Explanation: Minor concerns regarding adequacy of data (data comes mainly from one systematic review and one primary (theory-based) study)

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topic; d) assisting question formulation and reaching for consensus; and e) stimulating and guiding discussion (such as small group work, scenarios or hypotheticals, scoring methods, priority setting, workbooks, dialogue guide, voting, physical model, and court room format). It is also important to plan expert testimony, the nature of the expert evidence or the presenters' expertise, indicating that participants could engage with presenters and challenge the evidence. Within this process, HTA sponsors of the social engagement activities should elaborate a workbook to provide balanced relevant information that includes local research to present to the jury. It is also advisable that all written material is provided to jurors in advance, and organisers could also require participants to prepare questions (in this case, it is important to consider ethical analysis). Planning output formulation, reporting and dissemination of jury recommendations and findings is also essential — data collection (audio-record proceedings; contemporaneous notes by organisers or participants; workbooks; video-recording; whiteboard scribing; flip charts; voting; participant diaries; participant hand-held video-recording; questionnaires; interviews), qualitative data analysis (content analysis; close and repeated reading; discourse analysis; coding); recommendations (consensus; consensus with minority opinion; voting; no decision choice dominated); jury reports (written researchers based on participants' recommendations; jurors alone; facilitator assistance; researchers in consultation with participants); dissemination (media coverage; direct presentation to decision-makers; direct community engagement; planning meetings). The US experience outlined a few barriers to the implementation of citizens' juries, such as: a) administrative, financial and political constraints shaping the design and implementation of many community engagement strategies in real-world settings; b) restricting the use of citizens' juries to a narrowly defined set of parameters may preclude their use in policy processes or to inform practice reform; c) purity about the nature of the ideal deliberative process (methods are untenable within the constraints of the decision-making process) may impose a considerable loss to social engagement; d) strict adherence to and, in particular, legal regulation of a methodology, through patent or trademark, could be counterproductive for knowledge production since it is through testing and adapting methodologies that new ideas are developed and our understanding expands; e) reporting and improved evaluation of process and outcomes can only assist in ensuring that these methods are best designed to meet both democratic and instrumental goals. The US experience also outlined a few facilitators to the implementation of citizens' juries, such as: a) it is key to adapt citizens' juries to instrumental aims (particular care and attention should be paid to recruitment methods, independent oversight by a steering committee, jury duration, moderation and respect for the participant volunteer); b) juror selection can be dependent on formal requirement for 'citizenship' of the country in which the deliberation occurs; c) addressing juror-policy maker interactions — citizens have reported the need for greater 'accountability' by decision-makers who support deliberative forums so that citizens can feel that their input is wanted and is going to be needed; d) social engagement activities sponsors can use a range of techniques to promote the findings of the citizens' juries including academic literature, media channels and direct engagement with decision-makers.			

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Game/simulations have been used to fulfill principles of democratic deliberation — as in the FDA approach. Games and Simulations should be designed and pretested to ensure it is accessible and comprehensible to the widest possible spectrum of participants. The exercise should require low reading level and use other techniques to simplify complex material. Each participant in the exercise should have a fair opportunity to voice, and have considered, health care priorities that affect everyone, and the group discussion leader should be trained to actively solicit input from all members of the group, as the process of deliberation is designed to be systematic, transparent, and mutually respectful and to expose trade-offs to moral and rational assessment by individuals and by the group — the exercise seeks to provide an opportunity for 'advancing both individual and collective understanding'. In this sense, attempts to balance equity and efficiency should be facilitated as participants simultaneously weigh desired health technologies against the realities of resource constraints, promoting communal values while preserving individual autonomy (both individual and group preferences as values are solicited). Game and simulations exercises are designed for groups of nine to fifteen laypersons. Data and interaction (board) should be circular (similar to pie chart) and contain a wedge for each health technology that can be chosen by participants — circular design minimizes any presentation of a hierarchy of categories, and the relative sizes of the wedges graphically reflect approximate relative costs. Categories have varying levels (basic, medium, or high) of coverage that can be chosen by placing pegs in holes located within the wedges in the board, and social engagement sponsors should organize rules around how the game/simulation evolves (e.g. participants in the CHAT (Choosing Healthplans All Together) exercise receive fifty pegs, which allows them to fill in about 60 percent of the holes on the CHAT board). Barriers identified by the US experience with game and simulations: a) participants without health insurance enjoyed the game less (reporting anger and lower ratings of procedural justice); b) participants in worse health status (reported frustration, although informal adequacy scored higher); c) less educated participants reported more anger, less enjoyment, and less understanding of the exercise, but also more learning and rated informativeness and information adequacy more favourably. Facilitators to the implementation of games and simulations identified by the US experience: a) enjoyable, easily understood, informative, and engaging deliberative process; b) groups of persons without health care expertise and with a wide range of educational attainment and health care experiences, including a disproportionate number of those with low incomes and education, could use the game to design health plans acceptable to them and that fit within limited resources; c) engage citizens in discussions about the reality of limited resources and the necessary trade-offs. Nevertheless, it is important to outline that a three-hour CHAT session cannot possibly yield thoughtful, stable, just agreement regarding the medically and morally complex issues we identify during a simple direct tool of democratic choice for rationing and priority-setting decisions in healthcare today. This requires sustained rational democratic deliberation. In general, when we have clear and widely shared agreement that a specific principle of justice yields a just rationing or allocation protocol, we have no need for a deliberative process. However, when there are	(82,79)	Moderate confidence	Context: USA Explanation: Moderate concerns regarding adequacy of data (data comes mainly from two primary (case) study).

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conflicting or ambiguous intuitions of healthcare justice regarding novel therapeutic interventions, such as targeted cancer therapies or pre-implantation genetic diagnostics for IVF and a plethora of the novel procedures and technologies in Medicine today that generate deep social divisiveness related to conflicting value commitments, then we need a sustained fair process of democratic deliberation to construct a reasonable and "just enough" social response, as "fair terms of cooperation". This is how we revise and construct public reason in a liberal pluralistic, democratic society that must function with shared understandings of healthcare justice.			
Participatory research approach was implemented via Health Facility committees to bridge the gap between communities and health facilities. Committees promote accountability, co-management of resources, and health-seeking behaviours. Moreover, they act as advocates of the community and transmit the community's views to the facility. Barriers to engagement were the hierarchies (social, economic, cultural, geographic, and political) that existed previous to the formation of committees.	(88)	Moderate confidence	Context: Zimbabwe Explanation: Moderate concerns regarding adequacy of data (data comes mainly from one systematic review).
CITIZEN SCIENCE MODEL			
Regarding Citizen Science approaches to both Consultation and Participation Models, there is strong evidence that society should engage with all stages of (new) health technology development, assessment, implementation and monitoring and that HTA sponsors/organisations/agencies as well as the industrial sectors producing (novel) health technologies must receive citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates to inform HTA implementers, health professionals and decision-makers at research organisations and the private sector on their preferences for health care and their lived experiences on what works and does not work for them, as well as the costs and consequences (the impact) from using such health technologies. Societal experienced perceptions and attitudes are needed to combat lifestyle-related diseases and to promote compliance and self-efficacy through empowering strategies that help such stakeholders take greater responsibility for their own health status (biocitizenship) so that health systems stop giving them care that they neither want nor need. Therefore, citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates empowerment – as a process of enabling individuals to have control over their own health – requires: a) a system that relies upon antecedents, processes, and outcomes, which depends upon human capital and is facilitated by a patient-oriented system that not only accepts, but actively uses, their involvement; b) fully empowered patients that need to be informed, capable, and allowed to express their views; c) healthcare professionals who develop an open dialogue with patients to involve them directly in making informed decisions, and thus improve both their knowledge on medicine and access to services; d) access to healthcare needs to be promoted rather than rationed; e) information sharing needs to be promoted to develop the political will to provide this type of access. In this sense, HTA evolved predominantly in socialised health systems (Australia, Canada, UK), assuming some of the health systems' doctrines in these countries, namely: a) collective provision (UK's societal perspective from large randomised controlled trials generalisable to	(35,100)	High confidence	Context: All countries Explanation: Minor concerns regarding adequacy of data (data comes mainly from two primary studies)

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entire population); b) collective financing (of health care in Australia — scarce resources and opportunity cost despite continued drug costs growth); c) paternalism (methodological focus on quality-adjusted life-years (QALYs), often justified by the assumption of asymmetries of information, is merely the manifestation of the doctrine of paternalism particularly found in Europe — patients do not know what is good for them, so we need a 'special' formula to calculate it for them). Therefore, one of the biggest barriers to a citizen science approach to HTA comes from social institutions that have a vested interest in maintaining the status quo, hence it is important to note that all of these interests, whether it be from government, industry, academia, or medicine, should really only have one objective in mind — the well-being of the patient. Nevertheless, the environment is changing: Australia and The Netherlands have reformed their system to promote choice in health care and managed competition in healthcare markets. Furthermore, a series of facilitators have been identified, at the global level, for the implementation of empowerment-inspired citizen science approaches to social engagement with all stages of (new) health technology development, assessment, implementation and monitoring, as well as that of policy-making, such as: a) patient factors: empowerment (education and communication strategies, collaboration and trust, personal control of illness, support from families, acceptance of illness, hope); patient education (improve treatment adherence, improve health outcomes and satisfaction, misinformed behaviour via internet self-education requires individualised education interventions that adapts over time as patient gains more knowledge); b) staff factors: training to improve patient involvement (for more active role in share decision-making, self-care); information for involvement (promote proactivity and adherence, strategies — direct/indirect positive or negative reinforcement, relationship building, activation); c) organisational factors: service systems and technology (specialised centres; education programs with follow-up and educational opportunities; group sessions wit35h patients; chances for patients to meet other patients and their families; action research approaches; community engagement to maximise utility of scarce resources and strengthen patients; individual counselling on lifestyle issues and health measurements to help share decision-making processes, plan medication use in complex situations, supply data to providers and information support; online automatized reminders for treatment adherence; telemonitoring for patient activation).			
Regarding Citizen Science approaches to the Consultation Model, the global perspective outlines a series of methods that have been used to provide evidence of citizens'/consumers' qua patients' (and their families', carers', legal representatives') as well as advocates' preferences, such as: a) surveys of large patient populations; b) qualitative research (focus groups, interviews); c) literature searches to locate existing research that has identified preferences – the idea is to promote more active participation of citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates in the development of such consultation methods – i.e. soft/social technology or processes – so they can identify issues that are relevant to them. The global perspective has also identified a series of barriers to the implementation of consultation methods, such as: a) difficulties	(35,100,99)	High confidence	Context: All countries Explanation: No concerns for all CERQual components.

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aligning aggregate and personal preferences (personal preferences should inform clinical decisions 'regardless of the existing population-based preference data'); b) consumer choice rationale in health care has been critiqued for allowing public institutions and physicians to withdraw from their collective responsibility to ensure quality, efficiency and affordability of care and transfer responsibility instead to individual patients, the local community or the market; c) for guidelines, equating social engagement with the consideration of societal preferences for treatment options is limited in that it does not involve citizens/consumers and patients in determining the content, kind, number, quality and accessibility of the treatment options that may be available in the clinic in the first place; d) information (from protocols and guidelines) may disturb communicative behaviour due to power imbalances between citizens/consumer qua patients and professionals, and conflicting values; e) healthcare providers rarely use surveys in quality improvement work because the supporting values, infrastructure, and training are lacking. The global experience has further identified a few facilitators to the implementation of consultation methods, such as: a) instead of gold standards to be followed by doctors, guidelines should be reimagined as decision aids that provide (standardised) information on various options that physicians and their patients discuss, interpret, modify or ignore; b) guideline development organizations are producing additional tools such as patient versions and patient decisions aids to encourage the engagement of individual consumers to weighing their own options in clinical practice; c) patient organizations express a wish for guidelines not to be 'a forcing or demanding instrument' but 'primarily a tool to start a dialogue with the patient, so as to improve shared decision-making.			
Regarding Citizen Science approaches to the Participation Model, the global perspective identified a barrier to the implementation of citizens' juries/panels – engaging patient organisations (i.e. advocacy groups that are 'unrepresentative') may engender professionalisation, further undermining social participation as symbolic representation (tokenistic) and a facilitator to solve such issue – engaging patient organisations as collective organisation, representing lay expertise, which engender desired professionalisation to improve representation (although it may undermine independence), as expert witnesses.	(99)	Moderate confidence	Context: All countries Explanation: Serious concerns regarding adequacy of data (data comes mainly from one primary (case) study).
Regarding Citizen Science approaches to the Participation Model, the global perspective identified two facilitators for the implementation of stated preference elicitation, namely that: a) they are ideal for nonmarket or novel commodities and for developing new products, as their measurement can take the form of qualitative analysis (interviews/surveys), conjoint analysis (discret e choice modelling), willingness-to-pay (contingent valuation), and budget allocation games (i.e., asking patients to prioritize public funds); b) participants value all aspects of health care and not only utilities such as QALYs, as their stated preference methods are well supported by economic theory and can be used to provide a scientific support to what is often considered the 'soft-side' of HTA.	(35,99)	High confidence	Context: All countries Explanation: Minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies).
Community-Based Participatory Research (CBPR) is a Citizen Science approach to developing a Participation method for social engagement with HTA processes, often used synonymously with Participatory Action Research (PAR) and Action Research, which include participatory	(39)	Moderate confidence	Context: Africa, Bangladesh, Canada, China, India, Iran, UK, USA. Explanation: Moderate concerns

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approaches to health research. CBPR bridges the gap between research and practice through equitable engagement of the community to eliminate disparities in population health by addressing power imbalances and enabling knowledge exchange, resulting in its wide uptake as an appealing social engagement approach across various cross-cultural, diverse, and disadvantaged settings. Within CBPR context, Rapid Assessment Response and Evaluation (RARE – a component of PAR) constitutes a valuable public health research tool, particularly among ethnic populations, as it incorporates the use of datasets, community participation, and evaluation, and is most commonly used and successful social engagement method for ethnic and racial minority populations in health research studies (effective in achieving high retention rates also in data analysis, interpretation and/ or dissemination due to three key drivers: a) engagement of community partners in all stages of research development including dissemination of findings; b) facilitating knowledge exchange between community and academic partners; and c) achieving balance between research and action). Most of the barriers to social engagement in HTA implementation identified by the Canadian experience can be tackled by CBPR's various non-health related positive impact such as: building of social capital, community capacity building, empowerment of community members leading to community championship (external partner organisations achieved goals by facilitating trust-building between native and academic communities, facilitating referrals to social services, increasing the quality of local services, and enabling linkages with community resources), empowered and improved social networking and self-efficacy skills for participants. Facilitators to CBPR's implementation are: a) when CBPR is used in multi-ethnic samples, the approach needs to be tailored for each ethnic subgroup; b) partner input in intervention design, shared learning between academic and social partners, and bridging people on research teams; c) establishment of community advisory councils and collaborative partnerships involving accountability of stakeholders towards all project activities; d) real power-sharing between the community and research team including bidirectional learning; e) formative research for programme development and mobilisation of appropriate community resources; f) community involvement in research design and integration of culturally competent elements with the programme, including translations; g) training and ongoing support of bicultural community health workers; h) incorporating the voice and agency of indigenous and ethnic communities in the research protocol; i) enhancing the relevance of health promotion messages, fostering improved health behaviours, overcoming cultural and access barriers, and encouraging participant engagement; j) the combination of CBPR to develop collaborative partnerships and community health workers to deliver health interventions enabled community partners facilitated recruitment and training of community health workers, and community health workers to access 'hard to reach' participants experiencing health disadvantages enabling retention; and k) new partnerships between community, government and academic stakeholders, and the use of existing infrastructure such as faith networks, park authorities and tribal agencies were responsible for the post-intervention sustainability of programmes due to cultural acceptability, the existence of a historical collaborative partnership, and the			regarding adequacy of data (data comes mainly from one systematic review and there is no specific data extracted that could build this finding for each country in Africa as well as for Bangladesh, Canada, China, India, Iran, Uk and USA).

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engagement of an influential community partner such as a government organisation or tribal agency in all stages of the research.			
Regarding Citizen Science approaches to both development and implementation of the three models of social engagement, if we consider these as processes — i.e. soft/social technology[1,2] — after the UK and Canadian experiences, Australia is the country that is starting to implement financial, institutional and governmental investments to promote and support social participation strategies sponsored by health professionals and technology assessment and policy/decision-makers and organisations. The Australian experience provides innovative data on how consumer involvement in developing healthcare policy (laws, rules, financial and administrative orders made either by governments, non-government organisations or private organisations, that are intended to directly affect the provision and use of health services), research (clinical research, epidemiological research and health services research — investigating need, demand, supply, use, and outcome of health services), clinical practice guidelines (systematically developed statements to assist both practitioner and patient decisions in specific circumstances) and patient information material (included printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) has proved cost-effective to aid evidence-informed policy/decision-making within the realms of health technologies development, assessment, implementation and monitoring.	(49,40,60)	High confidence	Context: Australia Explanation: Minor concerns regarding adequacy of data (data comes mainly from two systematic reviews and one primary (case) study).
Canada has been in the vanguard of implementing a Citizen Science approach to all Information, Consultation and Participation models. Considering the three models of social engagement that our systematic review has proposed — Information (information and knowledge about a subject is provided and disseminated by researchers/HTA sponsors), Consultation (people provide data (e.g. in surveys or qualitative research interviews or focus groups) as HTA sponsors seek stakeholder views to influence decision-making), and Participation (society is actively involved in shared-decision-making with specialists and HTA sponsors/decision-makers) — citizen science means user-controlled social engagement activities. Therefore, citizens/consumers qua patients (and families/carers/legal representatives) and advocates can also input in the design, development, implementation and evaluation of methods for social engagement in HTA and coverage decision-making. Such is an interesting approach as HTA organisations/sponsors can both promote capacity building of HTA implementers, health professionals, policy/decision-makers and citizens/consumers qua patients (and families/carers/legal representatives) and advocates, and implement social engagement with their evaluation and decision-making processes that are already validated by end-users. Such processes have been termed, in Latin American readings of Social Studies of Science, Technology and Innovation as 'soft/social technology'. • **Several pilot studies have been both developed and implemented, following such citizen science approach, for the whole health technology development, assessment, implementation, monitoring and re-development cycle. In this sense, regarding health technology development, there should be earlier consideration of the impact of 'living with the disease' and using a health technology. Therefore, qualitative research should be**	(29,60,39,55,67,56)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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developed by the sponsor/industry, since the industry tends to historically focus mostly on quality of life (QoL) only, as well as by citizens/consumers qua patients (and families/carers/legal representatives) and advocates themselves. In this sense, their perspectives on the impact of HTAs should be included in the HTA sponsor dossiers. Regarding health technology assessment, the Canadian experience with the citizen science approach is that it not only widens the discussion about the role of HTA in health systems but also innovates and enables: a) education patient advocacy groups and HTA committees on the HTA process, considering new media options; b) development of new methods to reach citizens/consumers qua patients (and families/carers/legal representatives) and advocates; c) process transparency; d) documentation of meeting outcomes including the value of patient input and formal audit of the process; e) understanding values and citizens' priorities; and f) health literacy and the promotion of active and informed citizens/consumers. Regarding health technology implementation and monitoring, the citizen science approach enables: a) third-party facilitated discussion with citizens/consumers qua patients (and families/carers/legal representatives) and advocates; b) adding context to HTA data including QoL and more in-depth clinical outcome measures; c) timely notification of new products; d) time to commission research and ensure support for citizens/consumers qua patients engagement; and e) delivery of patient submissions and nomination of advocates to represent patients. Nevertheless, the Canadian experience identified legal and regulatory barriers associated with communication to patients that would need to be considered in many jurisdictions. Therefore, facilitators identified are ensuring that: a) views presented within HTA decision-making process are NOT biased or overrepresented; b) adequate (tailored) public/patient advocacy groups education programs; c) broader participation, feedback, transparency, flexibility and social media are prioritised. • **Consumer involvement in developing healthcare policy (laws, rules, financial and administrative orders made either by governments, non-government organisations or private organisations, that are intended to directly affect the provision and use of health services) and research (clinical research, epidemiological research and health services research — investigating need, demand, supply, use, and outcome of health services), clinical practice guidelines (systematically developed statements to assist both practitioner and patient decisions in specific circumstances) and patient information material (included printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) has proved cost-effective to aid evidence-informed policy/decision-making within the realms of health technologies development, assessment, implementation and monitoring.**			
Regarding Citizen Science approaches to the Consultation model, the Canadian experience outlines that, according to the characteristics of HTA organisations, some preferred consulting citizens/consumers qua patients independently rather than having them participate directly in the evaluation, while some did not feel at ease collecting data from patients. Furthermore, the greater the potential impact of a technology on a patient's quality	(55,67)	High confidence	Context: Cananda Explanation: Minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies).

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of life, the more relevant it was to involve them in assessing it. In this sense, since patients affected by the technology (or a close relative) should be involved in HTA consultation, evaluation of technologies with particular implementation, acceptability, feasibility and ethical issues requiring informed choice by patients would also benefit from patient consultation and/or their participation in the design of such consultation/participation methods.			
Regarding Citizen Science approaches to the Participation model, they outlined the relevance of having citizens/consumers qua patients (representatives from all health system users) participating at certain stages of the HTA process as members of the committee that designed the evaluation plan and discussed the final report and recommendations on all assessments (not only regarding a particular type of technology). In this sense, hospital managers and HTA producers considered that direct citizen/consumer qua patient participation was particularly relevant at certain stages of the HTA process, specifically, when elaborating the evaluation plan (specifying the research question, deciding what aspects to document and what main issues to consider) and at the discussion stage of the preliminary report and recommendations. Citizen/consumer qua patient participation was also considered important at the stage of disseminating the HTA reports, when patient input would help adapt information material to patient needs. Regarding citizen science's empowerment purposes, patient representatives and HTA producers underlined the importance of involving citizens/consumers qua patients (representatives) throughout the assessment process to improve patients' knowledge, give them a sense of responsibility for the decisions and increase their participation. Regarding recruitment, the Canadian experience outlined the need to select participants based on specific criteria, notably previous experience and qualities such as good understanding, judgment, listening capacity, respect and self-confidence to work in a multidisciplinary team. A facilitator, in recruitment, would be to include 'generalist patients', who would participate in all HTA committees, and 'specialist patients' who would participate on an ad hoc basis depending on the evaluation topic. There is also the option of recruiting citizens/consumers qua patients (representatives) in assessments (without being full members of the HTA committee) could provide a voice to health technology users without unduly increasing the time required and the complexity of the approach. The Canadian experience also observed that direct participation of citizens/consumers qua patients (representatives) in the HTA process seems to depend in part on the organizational culture and on the readiness of the HTA organisation. Therefore, the citizen science approach enables the co-production of not only citizens/consumers' qua patients' (representatives') and advocates participation in both design and implementation of HTA processes but also creates a culture that supports such an approach by all social actors with an interest in health technologies development, assessment, implementation, monitoring and policy-decision-making processes. The Canadian experience also describes that the type of social engagement should be determined on a project-by-project basis; therefore, a decision-making framework (as the one we present at this systematic review) can be useful in deciding whether social engagement is relevant in a specific context and how	(29,60,39,55,67,56)	High confidence	Context: Canada Explanation: No concerns for all CERQual components.

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to identify the most relevant strategies. The type of engagement may also change according to the stage in the HTA process: (direct) Participation methods of citizens/consumers qua patients (representatives) is more relevant at the beginning and end of the HTA process, whereas Consultation methods would be pertinent throughout the evaluation. Above all, the Canadian experience outlines the importance of evaluating social participation practices to provide evidence to inform future initiatives for introducing citizens/consumers' qua patient's perspective in HTA, and convincing managers of its relevance and utility. A few barriers have been recognised, namely that: a) there is low experience with the introduction of citizens/consumers qua patients' perspectives in HTA at the local level, therefore, HTA organisations and producers must be prepared to avoid diverting the focus of the evaluation towards less essential aspects, and the additional time and costs; b) biases and industry lobbies associated with some patient groups; c) lack of knowledge and tools to help with the integration of citizens/consumers' qua patient's perspectives in the HTA process; d) time constraints and additional workload, particularly if this activity requires the approval of an ethics review board; e) introduction of qualitative methods in HTA – usually based on a review of scientific (quantitative) evidence, safety and efficiency data and economic assessments – due to HTA producers fear of loss of control over HTA activities, which take place mostly within a well-defined framework; f) communication barriers; g) lack of participants' representativeness; h) intimidation of citizens/consumers' qua patients' representatives by HTA experts leading to decreased participation; i) lack of tools to support social participation; j) lack of feedback after participation; k) increased complexity due to multicultural and multilingual contexts. In this sense, facilitators identified are: a) clearly defining the objectives of social engagement to facilitate the integration of citizen/consumer qua patient information in the HTA report and recommendations; b) clear information on participants' role to help reduce the cultural barriers between citizens/consumers qua patients and HTA producers; and c) maintaining the same citizen/consumer qua patient representatives in committees for a couple of years to increase their knowledge and skills.			
Regarding Citizen Science approaches to a Participation Model that merges both health technology development and assessment to tackle the aforementioned drivers influencing the choice of social engagement model/methods undertaken by HTA organisations engagement processes, the HTAi experience outlines an interesting case study around the MEDICAL DEVICE TECHNOLOGY (MDT) DEVELOPMENT PROCESS (MDTDP). Considering the three models of social engagement that our systematic review has proposed — Information (information and knowledge about a subject is provided and disseminated by researchers/HTA sponsors), Consultation (people provide data (e.g. in surveys or qualitative research interviews or focus groups) as HTA sponsors seek stakeholder views to influence decision-making), and Participation (society is actively involved in shared-decision-making with specialists and HTA sponsors/decision-makers) — citizen science means user-controlled social engagement activities. Therefore, citizens/consumers qua patients (and families/carers/legal representatives) and advocates can also input in the design, development, implementation and evaluation of methods for social engagement in HTA and	(51)	Moderate confidence	Context: HTAi Explanation: Moderate concerns regarding relevance (partial relevance – approaches health technology assessment during health technology development) and serious concerns regarding adequacy of data (data comes mainly from one theory-based primary (case) study).

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coverage decision-making. Such is an interesting approach as HTA organisations/sponsors can both promote capacity building of HTA implementers, health professionals, policy/decision-makers and citizens/consumers qua patients (and families/carers/legal representatives) and advocates, and implement social engagement with their evaluation and decision-making processes that are already validated by end-users. Such processes have been termed, in Latin American readings of Social Studies of Science, Technology and Innovation as 'social technology'. In this sense, all processes whereby HTA organisations/sponsors/agencies deploy to engage society in decision-making and/or in the planning, design, governance and delivery of health care services about the social engagement intervention design, using methods of information, consultation, participation and/or citizen science (i.e. 'social control') can be termed as 'social technology'. Such approach hold the underlying belief that the social intervention will be more appropriate to the participants' needs as a result of incorporating all stakeholders' views. In this sense, by merging social engagement methods related to health technology assessment onto the health technology development process, national innovation systems can develop, implement and monitor (new) health technologies that have already been validated by citizens/consumers qua patients (families, carers, legal representatives) and advocates before they enter the market. This type of citizen science approach encompasses three stages with specificities related to the type of user — professional and/or end user — as follows: a) STAGE 1 — IDEA GENERATION & CONCEPT DEVELOPMENT: (1) PROFESSIONAL USERS (brainstorming sessions, ethnography, expert users meetings, focus groups, interviews, users - producers seminars); (2) END USERS (brainstorming sessions, ethnography, expert users meetings, focus groups, interviews, users - producers seminars); b) STAGE 2 — DEVICE (RE-)DESIGN & PROTOTYPE DEVELOPMENT: (1) PROFESSIONAL USERS (brainstorming sessions, in vitro tests, interviews, observations, think aloud method, usability tests, users — producers seminars, user feedback); (2) END USERS (in vitro tests, interviews, users — producers seminars, user feedback) and c) STAGE 3 — PROTOTYPE TESTING IN-HOUSE & TRIALS IN REAL FIELD: (1) PROFESSIONAL USERS (cognitive walkthrough, discussion with users, first human use, in vitro tests, interviews, observations, think aloud method, usability tests); (2) END USERS (discussion with users, first human use, in vitro tests, interviews, think aloud method, usability tests). The HTAi experience has identified a few barriers to the implementation of such an approach, namely that: a) practice has been very varied in involving users in the MDTDP and sometimes user involvement, particularly end user involvement, is very modest; b) low or limited user involvement could be due to several factors such as a lack of funds and time available to manufacturers who are operating in a very competitive market; c) it may also occur through the personal limitations of users (through cognitive, physical, or informational problems) to meaningfully participate in the MDTDP; d) willingness among manufacturers to use feedback from users' in the development of MDTs; e) poverty of effective frameworks to incorporate users' feedback in the MDTDP. Facilitators to the implementation of such type of citizen science approach have also been identified by the HTAi experience: a) if the medical device being developed is a			

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simple device that will be used by the end users then the END USER stream will be the first choice to develop such device (end users know their needs better than anyone else; end users and their lay carers might already have used a similar device at some point in time — they may have experience and knowledge of the limitations of using such a device), therefore, end users can be helpful in (re)designing and/or upgrading of existing devices as well as developing a new device that can be used for a similar purpose; b) healthcare professionals and professional carers can convey some of the needs and requirements of the end users (which they have come to know often through early contact with some of the end users) — manufacturers can, therefore, also involve professional users to get their perspectives about the device.			
Regarding Citizen Science approaches to the Participation Model, the Dutch experience reports on methodological notions for collaborations in mixed research teams, comprising professional researchers and patients as partner in response research – i.e. patient research partners or citizen scientists. In such endeavours, 'patient research partners' or simply citizens/consumers qua researchers can have the following roles/tasks: a) object or respondent (cooperates in clinical trial, shares information in interview or survey); b) advisor (brings experience, discusses new developments, evaluates scientific articles and research proposals (as referent), advises, manages research projects as member of scientific commission); c) interviewer/moderator (jointly composes surveys and topic lists, conducts interviews with patients, prepares and/or leads a focus group); d) research partner (jointly develops a design, gathers, analyses, and presents data, writes publications, evaluates articles and research proposals, participates in scientific congresses); e) research principal (initiates research, develops and maintains a knowledge base, joins established research networks). There are several methods of data collection/engagement for 'patient research partners', such as: a) in-depth interviews (preparations (topic list, recruitment), interviewer, analysis); b) open focus groups (preparations (topic list, recruitment), (co)moderator, analysis); c) focus groups for priority setting (preparations (protocol, recruitment), moderator, analysis); d) focus groups for formulating research questions (preparations (protocol, recruitment), (co)moderator, analysis); d) questionnaire (construction of questions, analysis). Implementation involves many steps, as each health research agenda-setting project can be coordinated by the first author who fosters the collaboration between the stakeholders, working with patient research partners. Regarding recruitment, candidates selection for 'patient research partners' should have personal experiences with the disease, be well informed about the illness experiences of other patients, and have a social network among patients and members of the patient association group. 'Patient research partners' together with professional researchers conduct participant observation, in-depth interviews and focus groups to prioritize research themes and to formulate research questions that should be tape-recorded, transcribed, and analysed by the team. Every activity should be carried out by at least one professional and one patient partner. Professional researchers and patient partners should coproduce a public-friendly (short and accessible) brochure with description of the critical moments in the illness and lives of patients, and the uncertainties	(36,30)	Moderate confidence	Context: Netherlands Explanation: Serious concerns regarding adequacy of data (data comes mainly from two primary (case) studies).

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patients face at these moments (distributed among members of the patient organization, respondents, and others with an interest in the project). Professional researchers and patient research partners should first interview patients and relatives to then moderate focus groups with clients and parents to get more in-depth knowledge about their issues (citizens/consumers should prioritize research theme at the last focus group by completing a questionnaire). Research partners should make an "easy-to-read" version of the report, using pictures so that people with reading problems could get an idea of the study and its results. Research partners should also be involved in the dissemination of findings (a research partner and a professional researcher can co-present the research on a national conference, jointly deciding on a "live" interview presentation: this creative format should embody their equal collaboration). Citizens/consumers qua patients (and their families, carers, legal representatives) as well as advocates should be approached via the membership of the participating citizen/consumer/patient/advocacy organisations websites, and all the respondents by letter about the project (data is to be gathered anonymised and before further dissemination, every respondent should receive an analysis to check the credibility of interpretation to prevent feelings of exploitation). Researchers' reflexivity: professional researchers must critically reflect on their experiences within the teams throughout the process, meeting monthly to discuss the proceedings in the teams and their own roles within them (research teams should regularly evaluate how teams are functioning (twice a month) via informal, oral evaluations (participant observation/recorded) and patient research partners should be interviewed at least twice by professional researchers (at the very beginning to investigate their expectations, and at the end to gain an understanding of their learning experiences)). The Dutch experience also identified a series of facilitators to the implementation of this citizen science approach to a participation method of social engagement with the whole cycle of a (new) health technology development, assessment, implementation and monitoring (for reassessment), which includes: a) starting with stakeholder group of least influence (patient research partners emphasised how important it is to create a safe and respectful working environment, especially in the beginning – otherwise they might have the idea that the most crucial decisions had already been made; they required a lot of support (felt uncertain and insecure about their "surplus value," and doubted whether they really would have a "say" due to a lack of experience with scientific research and the idea that science is about numbers, figures, and abstractions rather than about lived experiences, besides a tendency to look up to experts, and to question one's own experiential knowledge); support entails activities such as making time to have a cup of coffee to listen to their concerns, providing reassurance, adjusting time schedules, and helping them with difficult tasks); b) compensation (importance of offering a reimbursement for traveling and other expenses is also more or less self-evident – patient research partners received a small salary acknowledging and expressing appreciation for their efforts (an arrangement was made with patient research partners to prevent reductions in their allowance from the government); nonmonetary arrangements were also made (e.g. library access); prevention of overburdening patient research partners (travel time and duration of			

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meetings - patient partners can become fatigued easily, or lose their concentration when working continuously for a long time, requiring negotiations over the planning of breaks, acceptable work periods, and work schedules for them); patient research partners might fear the emotional impact of interviewing other patients, or it might cause them to recall painful moments in their own lives, and the confrontation with the suffering of others might evoke feelings of powerlessness and pity (appointment of counsellors to provide emotional support)); c) education and training (increases the expertise of patient research partners, which might enhance their self-confidence and feelings of security, fostering communication with professional researchers; professionalisation of patient research partners might induce them to lose touch with their fellow patients and/or 'representativeness' (worst situation is when patient research partner will not feel at home among researchers or fellow patients); concerns over sufficiency of purely technical scientific training (impression that one will only be taken seriously if one speaks the language of professionals, therefore, technical training might even disempower patients); training should focus on the empowerment of patients and offer them the opportunity to learn by doing, preferably as an "apprentice" to an understanding and knowledgeable researcher, in a climate of support and encouragement; patient research partners might also educate and train professional researchers (explaining the needs of patients as respondents in the research process, which methods are appropriate for certain patient populations, how to approach certain hard-to-find populations, and how to deal with patients as advisors or research partners), therefore, we should consider develop courses for both patients and professionals so that they can learn with and from each other); d) focusing on experiential knowledge (how patient research partners can help access experiential knowledge – data collection: open interviews; assistance with formulating appropriate questions and how to open a conversation with a respondents; open, conversational interviewing style; patient research partners played an important role in preparing, organizing, and facilitating the focus groups with patients/ clients and parents as their questions invited participants to relate their experiences (patient research partners connected with the group by bringing their experiential knowledge); patient research partners actively shared their own experiential knowledge during both data collection and analysis (while professional researchers tended to have a reductionist view, analysing themes separately in detail, patient research partners tended to emphasise the interrelatedness of themes; to illustrate the relationships between issues that emerged from experiential stories, abstract figures like "mind maps" (a global scheme) and "problem trees" (a detailed scheme with a strong emphasis on causal relations between issues) were made); e) interacting and mutual learning (core methodological notions in responsive research – as a process of naturalisation (metaphor emphasises that patient research partners held a lot of essential knowledge about a world unknown to professional researchers, preventing asking silly or even unintentionally belittling questions in interviews and focus groups; instructions and training sessions did not work very well (the research partners interviewed each other and got feedback from the researchers, but both groups felt this was not very productive), co-interviews with researchers helped patient research partners to develop the right attitude			

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(genuine curiosity, openness) and skills (listening, probing) for open interviews; patient research partners clarified specific language, symbols and rituals that surrounded people with the researched illnesses for both data collection and analysis (patient research partners had outspoken ideas about which patients/ clients should be consulted to gain a broad spectrum of experiences, and helped identify and acknowledge the dimensions of difference that matter to particular patient groups); the team could handle several fieldwork issues, because members were committed, open, and willing to listen to each other, and to adjust their attitude and behaviour (humour also helped reduce tensions), therefore, transdisciplinary teams that emphasises respect, trust, dialogue, and time are required to resolve conflicts when collaborations do not run smoothly); f) openness, respect, trust and engagement are stimulating for a dialogical process in which parties mutually learn from each other (these conditions cannot be commanded, but must be actively stimulated during the research process); g) reveal prejudices (patient research partners confronted professional researchers' own prejudices and vice versa); h) translate jargon (patient research partners helped professional researchers find simple words to replace complex, abstract language, helping reach out and contact patients, as well as increasing the response and improving the validity and dissemination of findings); i) acknowledges the patients' perspective (joint analysis of data with patient research partners helped professional researchers genuinely acknowledge the perspective of patients via co-analyses that helped better reflect the capriciousness of the illness experience and practical problems in daily life, and minimized risks of misrepresentation).			
Adapted version of the EUnetHTA Core Model questionnaire provided a comprehensive structure that guided individual or small group face-to-face or telephone discussions with all stakeholders to stimulate 'free-flowing' discussion of key issues across domains. Therefore, the Norwegian experience further specifies the importance of implementing approaches that fosters citizen's/consumer's qua patient's (and their families', carers', legal representatives') as well as advocates' activation to fully and profoundly engage with all stages of HTA processes, and further user-controlled research to improve such processes through shared-decision making. These shared-decision making processes must be adequately registered (collected), analysed and synthesised to inform and improve social engagement processes. In this sense, for collection, audio recording or note-taking are great options for registering discussions. Audio recordings must be fully transcribed and/or notes (all anonymised) are to be written up after each meeting. Each local coordinator should analyse data to identify key issues that will then be synthesized according to the EUnetHTA Core Model domains to structure findings from social engagement activities as an attempt to identify issues that could inform as many HTA assessment aspects and sub-questions as possible. It helps to produce a table listing the key issues within each of the EUnetHTA Core Model domains to be populated with the results from each of the local discussions and clustered into broad 'themes' using an approach guided by thematic analysis in qualitative research. COREQ (Consolidated criteria for reporting qualitative research) checklist can be used for reporting on qualitative research, and GRIPP (Guidance for Reporting Involvement of Patients and	(75,30)	Moderate confidence	Context: Norway Explanation: Minor concerns regarding adequacy of data (data comes mainly from two primary (case) studies).

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Public) checklist can be used for reporting on social engagement in decision-making processes for HTA purposes. The Norwegian experience outlines a series of facilitators to the implementation of social participation models, namely that: a) engagement requires consideration of targeted audiences' needs for access, support; b) engagement requires appropriate project information and questioning in a manner that enhances peoples' confidence in providing information/data; c) citizen's/consumer's qua patient's (and their families', carers', legal representatives') as well as advocates' can be viewed as 'colloquial evidence' that provides additional knowledge and has a different role to that of other types of evidence, hence, this type of knowledge should not be judged in the same way as other evidence because it is not collected in the same rigorous and systematic manner; d) it is important to overcome uncertainty about ethical requirements which vary in each country when undertaking social engagement, especially when using a consultation approach; e) both lay and professional stakeholders can contribute much experiential knowledge, assisting with decision-making methods' implementation; f) early engagement is a major strength as it assists the identification of issues that are common to various social groups and provides 'added value' as it enhances the likelihood of the findings having the adequate level of relevance.			
The UK has also been in the vanguard of implementing a Citizen Science approach to all Information, Consultation and Participation models. Considering the three models of social engagement that our systematic review has proposed — Information (information and knowledge about a subject is provided and disseminated by researchers/HTA sponsors), Consultation (people provide data (e.g. in surveys or qualitative research interviews or focus groups) as HTA sponsors seek stakeholder views to influence decision-making), and Participation (society is actively involved in shared-decision-making with specialists and HTA sponsors/decision-makers) — citizen science means user-controlled social engagement activities. Therefore, citizens/consumers qua patients (and families/carers/legal representatives) and advocates can also input in the design, development, implementation and evaluation of methods for social engagement in HTA and coverage decision-making. Such is an interesting approach as HTA organisations/sponsors can both promote capacity building of HTA implementers, health professionals, policy/decision-makers and citizens/consumers qua patients (and families/carers/legal representatives) and advocates, and implement social engagement with their evaluation and decision-making processes that are already validated by end-users. Such processes have been termed, in Latin American readings of Social Studies of Science, Technology and Innovation as 'soft/social technology'. In this sense, all processes whereby HTA organisations/ sponsors/ agencies deploy to engage society in decision-making and/or in the planning, design, governance and delivery of health care services about the social engagement intervention design, using methods of information, consultation, participation and/or citizen science (i.e. 'social control') can be termed as 'social technology'. Such approach hold the underlying belief that the social intervention will be more appropriate to the participants' needs as a result of incorporating all stakeholders' views. Therefore, peer-lay-delivered social engagement interventions is	(60,46,96,9,39,67,30,56)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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facilitated by the credibility, expertise or empathy that the (target) community member can bring to the delivery of the intervention, as an empowered community is the product of enhancing their mutual support and their collective action to mobilise resources of their own and from elsewhere to make changes within the community. Empowerment models require that the health need is identified by the (target) community and that they mobilise themselves into action by following self-developed guidelines, further reducing health inequalities and attaining sustainability. • **Several pilot studies have been both developed and implemented, following such citizen science approach, for the whole health technology development, assessment, implementation, monitoring and re-development cycle. In this sense, regarding health technology development, there should be earlier consideration of the impact of 'living with the disease' and using a health technology. Therefore, qualitative research should be developed by the sponsor/industry, since the industry tends to historically focus mostly on quality of life (QoL) only, as well as by citizens/consumers qua patients (and families/carers/legal representatives) and advocates themselves. In this sense, their perspectives on the impact of HTAs should be included in the HTA sponsor dossiers. Regarding health technology assessment, the UK experience with the citizen science approach is that it not only widens the discussion about the role of HTA in health systems but also innovates and enables: a) education patient advocacy groups and HTA committees on the HTA process, considering new media options; b) development of new methods to reach citizens/consumers qua patients (and families/carers/legal representatives) and advocates; c) process transparency; d) documentation of meeting outcomes including the value of patient input and formal audit of the process; e) understanding values and citizens' priorities; and f) health literacy and the promotion of active and informed citizens/consumers. Regarding health technology implementation and monitoring, the citizen science approach enables: a) third-party facilitated discussion with citizens/consumers qua patients (and families/carers/legal representatives) and advocates; b) adding context to HTA data including QoL and more in-depth clinical outcome measures; c) timely notification of new products; d) time to commission research and ensure support for citizens/consumers qua patients engagement via NICE's and SMC's various participation methods; and e) delivery of patient submissions and nomination of advocates to represent patients. Nevertheless, the UK experience identified legal and regulatory barriers associated with communication to patients that would need to be considered in many jurisdictions. Therefore, facilitators identified are ensuring that: a) views presented within HTA decision-making process are NOT biased or overrepresented; b) adequate (tailored) social/patient advocacy groups education programs; c) broader participation, feedback, transparency, flexibility and social media are prioritised. Nevertheless, there is no gold standard approach for social engagement neither in the UK nor across Europe, but the UK experience indicates this can be done successfully in a variety of different ways, using a variety of different approaches/methods — researchers and HTA implementers/sponsors should only consider understandings about social engagement in the local context when**			

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undertaking this in more than one country as some approaches/methods may be considered more appropriate than others. In this sense, other facilitators to the implementation of citizen science approaches to social engagement activities within the UK experience are: a) training in research and evaluation methods for patients, carers and the public who want to dialogue with decision makers facilitates their empowerment; b) both lay and professional stakeholders can contribute much experiential knowledge, assisting project development; c) engaging stakeholders early in project development in European countries was a major strength as it assisted the identification of issues that were common across countries, providing 'added value' as it enhances the likelihood of the findings having international relevance; d) stakeholder information can inform project decision-making about both the intervention and comparator used in the main HTA research question and the focus of sub-questions used to assess other aspects in the project/technology — potentially enhancing the applicability of project findings/technology.			
Regarding Citizen Science approaches to the Consultation model, there is no recommended approach to social engagement and, although clear methodologies exist when using qualitative research approaches, this is not the case for stakeholder consultation. Nevertheless, the UK experience outlines the importance of: a) identifying topics via permanent online forms open to all, and networks/ forums with research organisations (e.g. James Lind Alliance), user groups and charities (suggestions from experiences of particular health issues or conditions); b) prioritising topics as reviewers of briefs (potential topics expanded into written briefs to inform decision-making; briefs sent to experts in relevant field(s) for comments, including at least one public reviewer; reviewers comment on relevance and importance of evidence gap, knowledge potentially generated, and indicate support or otherwise); and c) commissioning (funding) board to fund most competitive proposals via academic (health professionals and methodologists) peer-review (no public membership — given at prioritisation) and public referees invited to submit written comments on full proposals (peer-review process: commissioning board also makes assessment if the social engagement proposed in the trial is adequate, given public reviewer's advice). All such Consultation activities can be done as focus group meetings and face-to-face/telephone interviews, as well as written in person and/or online questionnaires/surveys to be completed by all who hold an interest in the health technology subject under evaluation, and they should: a) be outcome-focused (people need to know they can make a difference and that they are not wasting their time); b) be patient-led (citizens/consumers qua patients (families/carers/legal representatives) and advocates should be the ones driving the whole social engagement agenda forward); c) be representative but not targeted (HTA organisations/implementers/sponsors need to make sure it is not just the patients who want to complain who they hear from); d) have a variety of methods for understanding views needed (questionnaires are good for waiting rooms; however, alternatives should include print-outs as it is cheaper — than telephone, for example; setting up a website for feedback and really publicise it with a countdown of how	(46,96,39,67,30,56)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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many days for people to have their say); e) give feedback (people don't mind giving their opinion but HTA sponsors have to explain why they want it and how it will be used); f) involve those with power (initiative from politicians, unions and employers to raise the awareness of how society can contribute). Questionnaires can be used to provide comprehensive guidance for individual or small group face-to-face or telephone discussions with all stakeholders to stimulate 'free-flowing' discussion of key issues across domains during focus groups. Audio recording or note taking for discussions to be transcribed and/or notes (all anonymised) to be written up after each meeting. Local engagement sponsor to analyse data to identify key issues and synthesise findings. There are various ways of analysing collected data as part of qualitative research approaches — it would be interesting to use COREQ (Consolidated criteria for reporting qualitative research) checklist for reporting on qualitative research, and GRIPP (Guidance for Reporting Involvement of Patients and Public) checklist for reporting on social engagement in research. The UK experience has also identified a few barriers to developing and implementing citizen science approaches to the Consultation model, such as: a) engagement at the individual level has different meanings for different categories of people; b) collectively, there may not be great difference in expectations between different categories of people; c) involving stakeholders required consideration of their needs for access, support; appropriate project information and questioning in a manner that enhanced their confidence in providing information/data; d) stakeholder perspectives can be viewed as 'colloquial evidence' that provides additional knowledge and has a different role to that of other types of evidence (some researchers suggest that this type of knowledge should not be judged in the same way as other evidence because it is not collected in the same rigorous and systematic manner); e) given different stakeholders' roles and relationships with researchers and HTA sponsors, HTA organisations responsible for hosting social engagement activities should overcome uncertainty about ethical requirements which vary in each country when undertaking social engagement, especially when using a consultation approach; f) while using different methods of social engagement was a strength in terms of being locally appropriate, it proved challenging in terms of synthesis; g) limitations exist in the reporting of differences in professional and lay perspectives across [European] countries.			
Regarding Citizen Science approaches to the Participation model, the UK experience has identified a series of variables that are key to socially constructing engagement activities within HTA processes. First, it is important to outline that the HTA community conceptualises social engagement according to: a) characteristics of the technology being assessed (project-by-project basis, stage of development, potential implications, and purpose and timing of assessment); b) HTA agency's institutional context (resources, mandate, accountability and HTA networks); c) interests of stakeholders involved; and d) HTA community's ideas regarding health technologies, HTA (knowledge, deep-rooted values, beliefs and expectations) and social engagement (domains, types of public and levels of involvement). Second, it is essential to consider the domains of engagement: a) policy domain (society can: help to define coverage policies and decisions, create a more educated, empowered, and	(60,46,96,9,39,67,30,56)	High confidence	Context: UK Explanation: No concerns for all CERQual components.

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engaged community, increase trust and understanding among stakeholders; and secure buy-in for contentious decisions); b) organisational domain (promoted as a means of achieving informed, transparent, and accountable agency decisions); and c) research domain (process of designing, conducting and documenting assessments (includes framing research questions, elaborating an HTA protocol, identifying the outcomes of interest, collecting and appraising the evidence, and writing and reviewing HTA reports) — social engagement can help answer the right types of questions and produce the right types of services by making HTA reports more relevant and closely aligned to public values, needs, and preferences to increase compliance, satisfaction and overall wellness). Third, it is adamant to consider the types of stakeholders — HTA agencies/sponsors need to enable average citizens, patients, and service users to participate into two categories: a) publics representing a societal or lay perspective about health technologies (citizens, groups representing citizens, and elected officials) to be involved in 'generic processes' of the policymaking and organisational domains; and b) publics representing those directly affected by a given health condition or technology (individual patients and service users and their representatives) are more likely to be involved in the research domain (better positioned to highlight matters relevant to patients and service users). Fourth, HTA organisations/sponsors must plan the levels of engagement that they will develop for: a) receiving or seeking information (HTA agencies do not seek public input but rather disseminate information — e.g., plain-language HTA reports sent by mail — or make information available to those who seek it — e.g., on agencies' websites and in public board meetings); b) providing data (society provides data about values, needs and preferences to inform different phases of the HTA process), commenting (public provides comments that inform the HTA process through consultative mechanisms open to those who may be affected by the health condition or the technology in question (voluntary process) and collaborating (society collaborates with the HTA agency, providing guidance and advice (more active role) but HTA agency retains decision-making authority); c) appealing (society can appeal for a review or a reversal of an agency recommendation — only possible if HTA agency's governance structure includes a recommendation review mechanism; if appeal is considered valid, the agency is obliged to respond); and d) participating (society shares decision-making authority, exerting direct influence (most common way is by participating in advisory committees – more innovative mechanisms, such as citizens' juries and consensus conferences are promoted by certain HTA agencies to inform coverage policies and decisions, set the agency's strategic directions, and determine priority-setting, commissioning, and dissemination activities), and designing and reviewing research protocols, conducting assessments, and interpreting results; e) controlling (public controls certain phases of the HTA process or the process itself (only happens if public has complete decision-making authority, which is rare). In this sense, it is important to consider the authoritative role of policy communities in the development of a common understanding of social engagement in HTA (links between HTA agencies and other organizations (governmental departments and international organizations) are also identified as powerful institutional influences). • The UK experience identified a series of barriers to the implementation of Citizen Science			

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approaches to Participation methods, such as: a) institutional constraints make it unlikely that HTA agencies/sponsors will change their processes and procedures to allow for greater social engagement; b) scarce human and financial resources; c) fear that engaging the society may cause HTA agencies/organisations to deviate from their mandate to synthesise the evidence, and constant pressure to produce quick and efficient HTAs; d) claims that HTA is still immature and that theory lags behind practice (purpose and epistemological basis largely undertheorized) support contestation of social engagement; e) greater social engagement implies opening the doors of HTA agencies/organisations and sharing power and resources with other stakeholders (weigh professional and organisational interests against those of social representatives, and protect the scientific legitimacy and apolitical status of HTA agencies/organisations by limiting societal role); f) society is usually engaged too late, once the HTA report has been prepared; g) political sensitivity in the establishment of HTA agencies/organisations' strategic priorities (most agencies/sponsors' mandate is to advise decision-makers, therefore mobilising society could create expectations that decision-makers are unable to fulfil); h) concerns about social engagement with the research domain as most issues are technical; i) reluctance to engage representatives of patient and service user groups for: i.1) fear that they are biased towards the needs of their member-groups representing patients, i.2) service users are often affiliated with the health technology industry, i.3) organised groups encourages professionalization of society through the repeated involvement of individuals closely associated with HTA agencies/sponsors and other governmental institutions; j) concerns with possible pitfalls of more engagement, especially in the research domain — trying to engage with society more actively could result in a token form of engagement, or, worse, compromise the scientific integrity of the HTA process — social engagement should not be a "free-for-all" (informant's term), but rather structured so as to optimise the HTA process (desire to avoid disrupting current HTA procedures, and reflect inherent tensions between democratic and scientific approaches to social engagement). Specifically regarding NICE, their Citizens Council exert a high degree of control over their activities, as they have the authority to question expert witnesses and commission research papers; however, it was difficult not only for Citizens Council deliberations to be translated into the work of NICE but also to create the 'expertise space' necessary for Council members to deliberate meaningfully. The UK experience has also identified a series of facilitators to the implementation of citizen science approaches to Participation methods, such as: a) hosting themed-calls for health technology assessment helped support prioritisation of topics and methods assessment (useful advice on methods; feedback for development of user-friendly documentation; need for clear discussion on importance of proposals to the NHS, rather than just on scientific quality, helping strengthen the committee's working practices); b) compulsory social engagement worked as catalyst for uptake of engagement strategies by researchers and industry; c) acceptability (community-designed or -delivered interventions, or culturally relevant programme materials, were linked to acceptability, which influenced health technology implementation success); d) consultation/participation methods that			

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established successful partnerships and efforts to build relationships between partners appear to influence health outcomes; e) costs (paying community members and participants influences participation; some coalitions were able to win external funding, helping the programmes to be sustainable and 'owned' by communities beyond initial funding periods); f) implementation (adequate and appropriate intervention timing, frequency, duration and extent of an intervention influence outcomes; intervention types (e.g. media events vs. one-to-one counselling) can affect accessibility or 'reach' by enabling exposure to different numbers (and potentially groups) of people; good relationships between engagees and professionals providing health technology are important for their implementation); g) good project management and specific, adequate, ongoing training and support for engagees impacts on health technology implementation; h) peer-/lay-delivered approaches (involves services engaging communities, or individuals within communities, to deliver interventions — in this model, change is believed to be facilitated by the credibility, expertise or empathy that the community member can bring to the delivery of the intervention — e.g. home visitation to encourage mothers to breastfeed) have large effects over a narrow range of outcomes, as opposed to empowerment models that might have smaller effects over a broader range of health and social outcomes. • **Consumer involvement in developing healthcare policy (laws, rules, financial and administrative orders made either by governments, non-government organisations or private organisations, that are intended to directly affect the provision and use of health services) and research (clinical research, epidemiological research and health services research — investigating need, demand, supply, use, and outcome of health services), clinical practice guidelines (systematically developed statements to assist both practitioner and patient decisions in specific circumstances) and Patient Information Material (included printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) has proved cost-effective to aid evidence-informed policy/decision-making within the realms of health technologies development, assessment, implementation and monitoring.**			
Regarding Citizen Science initiatives on all Information, Consultation and Participation models, the US experience is less extensive than that of both the UK and Canada. Nevertheless, there are a few quite interesting initiatives. Regarding the Consultation model, there are the Patient-Centred Value Model Rubric and the Patient Activation and Engagement (PAE). Regarding the Participation model, there are the Community-Based Organisations (CBOs) and Community-Based Participatory Research (CBPR) that deploy Participatory Action Research (PAR) method to foster not only the active participation of stakeholders in the evaluation process but also the control of decisions, on the part of key stakeholders, in planning, designing, and implementing the evaluation. In this sense, the implementer/researcher becomes a coach, a partner, a provider of technical assistance, or an agent who plays multiple roles — as in citizen science initiatives, where evaluation research becomes a genuinely collaborative process with an emphasis on utilisation. Therefore, citizens/consumers qua patients (and families/carers/legal representatives) and advocates	(78,80,81,39,56)	High confidence	Context: USA Explanation: No concerns for all CERQual components.

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can also input in the design, development, implementation and evaluation of methods for social engagement in HTA and coverage decision-making. Such is an interesting approach as HTA organisations/sponsors can both promote capacity building of HTA implementers, health professionals, policy/decision-makers and citizens/consumers qua patients (and families/carers/legal representatives) and advocates, and implement social engagement with their evaluation and decision-making processes that are already validated by end-users. Such processes have been termed, in Latin American readings of Social Studies of Science, Technology and Innovation as 'social technology'5,6. In this sense, all processes whereby HTA organisations/sponsors/agencies deploy to engage society in decision-making and/or in the planning, design, governance and delivery of health care services about the social engagement intervention design, using methods of information, consultation, participation and/or citizen science (i.e. 'social control') can be termed as 'social technology'. Such approach hold the underlying belief that the social intervention will be more appropriate to the participants' needs as a result of incorporating all stakeholders' views. • **Consumer involvement in developing healthcare policy (laws, rules, financial and administrative orders made either by governments, non-government organisations or private organisations, that are intended to directly affect the provision and use of health services) and research (clinical research, epidemiological research and health services research — investigating need, demand, supply, use, and outcome of health services), clinical practice guidelines (systematically developed statements to assist both practitioner and patient decisions in specific circumstances) and Patient Information Material (included printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) has proved cost-effective to aid evidence-informed policy/decision-making within the realms of health technologies development, assessment, implementation and monitoring.**			
Regarding the Citizen/Consumer qua Patient-Centered Value Model Rubric as a Citizen Science approach to a Consultation method, the US experience outlines six domains. First, HTA sponsors should ensure citizens/consumers qua patients (and families/carers/legal representatives) and advocates partnership so that: a) society should be involved in every step of the development and dissemination processes; b) meaningful social engagement engenders patients being recognized as partners and integrated in all aspects of development — 'high' rubric (patient input is sought and used throughout, from planning to updating), 'low' rubric (patients respond only as part of a public comment period); c) society is engaged in pilot testing and refinement — 'high' rubric (a patient advocacy group partners with a payer to test in practice), 'low' rubric (no pilot testing with patient input). Second, HTA sponsors should ensure transparency, so that: a) assumptions and inputs (and each step in the process) should be disclosed in an understandable way and in a timely fashion; b) meaningful patient engagement is attained when members from society have early opportunities for review of and comment on inputs, methods, and drafts through multiple venues — 'high' rubric (society is given more than two opportunities to provide comment without undue limitations on length or time), 'low' rubric (society is given one opportunity to	(78,71)	High confidence	Context: USA Explanation: Minor concerns regarding adequacy of data (data comes mainly from one primary (case) study).

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
provide input after the draft was fully developed); c) purpose and goals are made clear to society (including the intended audience and use) and are well defined — 'high' rubric (the goals of the model are clearly represented and understandable to patients), 'low' rubric (the goals of the model are not clear to society and do not include implications for them). Third, HTA sponsors should ensure inclusiveness of citizens/consumers qua patients (and families/carers/legal representatives) and advocates so that: a) perspectives drawn from a broad range of stakeholders, including the patient community, should be reflected; b) representatives society are involved throughout the process ensure a meaningful social engagement activity, as required or expected given the condition/ population — 'high' rubric (a rationale is provided for societal perspectives sought and incorporated throughout the process), 'low' rubric (input is sought from stakeholders without consideration of the type of stakeholders that would be most appropriate given the condition/ population); c) the draft is vetted with a broad coalition of stakeholders, including patients — 'high' rubric (a broad coalition of patient organizations is given appropriate time to vet), 'low' rubric (notification of public comment period(s) is not widely distributed). Four, HTA sponsors should ensure diversity of populations so that: a) differences across subpopulations, trajectory of disease, and stage of a citizen/consumer qua patient's life should be accounted for; b) diversity of population is acknowledged and considered in meaningful social engagement activities — 'high' rubric (consideration was given to differences in societal perceptions of value across relevant subpopulations, including populations at risk and those with early- and late-stage disease), 'low' rubric (the model assumed the population is homogeneous and takes a "one size fits all" approach); c) applicability and limitations across subpopulations and disease trajectory are acknowledged and considered — 'high' rubric (information was provided on limitations with regard to the younger patient subpopulation), 'low' rubric (limitations regarding applicability in the younger subpopulation are not addressed). Five, HTA sponsors should ensure outcomes society cares about so that: a) outcomes integrated should include those that stakeholders have identified as important and consistent with their goals, aspirations, and experiences; b) outcomes important to society are identified and incorporated in meaningful social engagement activities — 'high' rubric (a clear link was described between the outcomes incorporated and their importance to society), 'low' rubric (only clinical outcomes are considered without the context of importance to society); c) processes are in place for identifying and incorporating emerging information on outcomes of importance to society — 'high' rubric (a mechanism is described that allows all stakeholders to suggest when an update is needed), 'low' rubric (no mechanism was offered for people to suggest when an update is needed). Six, HTA sponsors should ensure citizen/consumer qua patient-centered data sources so that: a) various credible data sources are used allowing for timely incorporation of new information and account for the diversity of populations and citizen/consumer qua patient-centered outcomes, especially those from real-world settings and reported by citizens/consumers qua patients directly; b) existing sources of citizen/consumer qua patient-generated health data (e.g., patient registries or PROs — Patient-Reported Outcomes) are identified and considered — 'high' rubric (data on			

REVIEW FINDING	CONTRIBUTING STUDIES	CONFIDENCE IN THE EVIDENCE	EXPLANATION OF CONFIDENCE IN THE EVIDENCE ASSESSMENT
PROs are used, and the sources well described), 'low' rubric (no effort is made to identify sources of patient-reported data on physical function, although this was identified by patients as the outcome of highest priority); c) data beyond randomized controlled trials are considered (e.g., natural history, patient views, outcomes and/or treatments, preferences regarding outcome or treatment) — 'high' rubric (the report describes all data sources used, including data from a patient registry), 'low' rubric (included only clinical trial data submitted to the FDA as part of a new drug application). The US experience with the Citizen/Consumer qua Patient-Centered Value Model Rubric as a citizen science approach to a Consultation method has identified a few barriers to its implementation, namely that, a) the rubric content was based on the roundtable discussion and vetting among a group of peer reviewers; b) participants and reviewers were a convenience sample who had been recommended by the roundtable participants — may not have captured the views of all stakeholders or the breadth of representation within any one stakeholder group; c) the rubric has not been formally tested and needs to be used by various stakeholders to fully capture its utility, validity, and impact; d) although the domains of citizen/consumer qua patient centricity and examples of 'high' versus 'low' social engagement may be broadly applicable, this initiative was developed in the context of the US health care system and frameworks recently published in the United States, so it may require cultural adaptation before its use by international audiences.			
Regarding the Patient Activation and Empowerment (PAE) method, as a Citizen Science approach to a Consultation method, the US experience outlines the telephone/in person surveys' utility in: a) increasing the use of in-home monitoring devices, developing patient portals to enhance two-way communication (particularly true in developing patient portals and tailoring messages to facilitate greater communication with patients; b) limiting data about people to personalize information and therefore make it feel more relevant personally to them; c) embedding care managers (often nurses or medical assistants) into the practice itself, developing patient portals, patient-to-patient peer coaching, expanding use of in-home monitoring devices, and increasing patient involvement in quality improvement, and practice redesign; d) modulating four external factors — payment reform, insurance coverage/benefit design, information technologies, and broad population health interest — that might facilitate expansion of PAE activities beyond the current base of early adopters.	(80)	High confidence	Context: USA Explanation: Minor concerns regarding adequacy of data (data comes mainly from one primary (case) study).

5 Tomada de Decisão Informada

Quando se trata do engajamento da sociedade na área de saúde pública, o primeiro e mais fundamental aspecto a ser considerado, sobretudo num país com extremas desigualdades sociais e regionais como o Brasil, é o seguinte: o acesso é uma forma crucial de envolvimento. Mesmo que uma tecnologia e procedimento seja introduzido no sistema de saúde por meio de uma discussão social abrangente e rica, isso seria insuficiente, do ponto de vista da cidadania, se não fosse garantido largo acesso a tal tecnologia ou procedimento.

Para além dessa questão básica, muitos estudos têm demonstrado que, sempre que uma tecnologia se integra ao sistema de saúde por meio de um debate amplo, com a garantia de participação social, os resultados produzidos por essa tecnologia se mostram mais favoráveis, tanto do ponto de vista da saúde biológica como do ponto de vista da cidadania27,13,31,32. Sendo assim, medidas que tragam ao sistema de saúde brasileiro instrumentos de verdadeira participação (e não apenas informação e consulta) se fazem crescentemente importantes. Nesta segunda parte deste relatório, discutiremos como esses instrumentos podem ser operacionalizados num país grande, desigual e diverso como o Brasil, trazendo recomendações.

Antes de passar às considerações mais específicas, porém, é preciso considerar um aspecto geral decisivo: modelos de participação social devem ser permanentes, já que eles implicam um processo de aprendizado coletivo. O que apresentamos abaixo tem por vista implementar processos participativos para matérias pontuais e temporárias, mas, conforme apontaram Moran e Davidson (2011)[46], processos participativos devem ser constantes, ou seja, é fundamental que esses processos pontuais e temporários sejam repetidos várias vezes. Desse modo, aprendizados podem ser incorporados, de modo que novas iniciativas de participação sejam mais robustas, inclusivas e eficazes do que as iniciativas anteriores.

5.1 Experiências Brasileiras

É sabido que no Brasil ainda não foram aplicados processos participativos de avaliação de tecnologias de saúde tais como os que existem, por exemplo, no Reino Unido, Canadá e Alemanha. Tudo o que se fez, até o momento, foi a utilização de consultas públicas, que, como visto na primeira parte, não constituem esquemas de participação social propriamente ditos. Apesar dessa deficiência política e administrativa, o Brasil possui uma série de experiências administrativas, políticas e cívicas que poderiam ser aproveitadas nos modelos participativos a serem elaborados daqui para frente:

d. pessoas são recrutadas para compor júris públicos em tribunais
e. pessoas que fazem doação espontânea de sangue têm direito a um dia de folga no trabalho, sem prejuízo de remuneração
f. nas eleições, o Brasil elaborou um sistema digital muito eficiente de coleta e apuração de votos
g. na cidade de Porto Alegre, foi utilizado um sistema bem-sucedido e internacionalmente reconhecido de orçamento participativo

Apesar das diferenças entre essas experiências, todas elas apontam para um ato de cunho comunitário em que os indivíduos participantes de alguma forma doam seu tempo e energia a atividades que não trazem benefício imediato para si próprios, mas que visam à melhoria da vida coletiva. Assim, alguns aspectos dessas experiências podem servir de inspiração para modelos de participação em avaliação de tecnologias de saúde. Por exemplo, poderia ser testado um método por meio do qual os indivíduos que participem de um processo participativo presencial tenham direito a um dia de folga no trabalho. Além disso, poder-se-ia pensar numa espécie de plebiscito participativo em que alguns participantes seriam convidados a expressar seu voto, com uma apuração eletrônica dos resultados.

Vamos abordar os métodos de participação, concretamente, num momento posterior. Por ora, queremos somente destacar que o Brasil já possui experiências que, se estudadas com mais cuidado, podem iluminar a montagem de modelos brasileiros de participação social.

Não se deve concluir que, por causa de seu atraso, o Brasil deva simplesmente copiar o que já se tem feito noutros países. Os mesmos modelos de participação social levam a resultados diferentes quando aplicados em outros países[43]. Quando se tentam importar modelos de participação, os resultados costumam ser desfavoráveis[47]. Então, cabe ao Brasil encontrar seus próprios métodos e refiná-los, uma tarefa que vai certamente exigir um esforço continuado e criatividade. Ao longo desse esforço, não se podem desprezar experiências disciplinares e culturais que têm buscado, ao longo dos anos, justamente suscitar uma reflexão coletiva. Por exemplo, as técnicas do Teatro do Oprimido, desenvolvidas por Augusto Boal, revelaram-se muito poderosas (e de baixo custo) na incitação de debates coletivos em que são questionadas prioridades e valores. Por que não utilizá-las, por exemplo, nos passos iniciais de um processo deliberativo coletivo?

5.2 Diretivas Iniciais de Participação Social

O objetivo principal deste relatório foi trazer os resultados da revisão sistemática realizada nos últimos meses. Ao longo desse trabalho, foi possível recolher uma série de ideias e exemplos que inspiraram uma reflexão inicial sobre mecanismos de participação no Brasil. Essa reflexão não é suficiente para que se possam indicar 'modelos exatos e infalíveis' a serem aplicados no Brasil. Como já dissemos, o desenho de esquemas participativos é um exercício prático, que deve ser realizado sucessivas vezes, num constante processo de aprendizado e refinamento. O que apresentamos nos sete itens seguintes não constitui, portanto, uma receita pronta; trata-se, antes, da apresentação de diretivas iniciais que podem nortear a construção de processos participativos no Brasil.

5.2.1 Os Tempos da Participação Social

Em se tratando da duração das iniciativas de participação, pode-se pensar em duas modalidades:

h. iniciativas de curta duração. São aquelas em que os cidadãos são chamados a contribuir para a avaliação de um certo medicamento, procedimento, equipamento ou protocolo específico. Essas iniciativas têm uma duração predeterminada, podendo durar alguns dias ou mesmo alguns meses. Um exemplo seria uma consulta pública que fica disponível na internet por um certo período (consulta). Outro exemplo seria a constituição de um júri público programado para alguns dias (participação).
i. esquemas constantes. É enganoso pensar que, uma vez terminadas as iniciativas de curta duração, todas as questões discutidas ficarão pacificadas para sempre. Novas dúvidas, reivindicações e contestações poderão aparecer, mesmo porque as tecnologias vão mudando de sentido e uso ao sabor das mudanças tecnológicas, econômicas e sociais. Desse modo, é importante que existam canais (e-mail, website, telefone e outros) sempre abertos ao público, ao qual ele pode direcionar suas perguntas e demandas. Esses canais, que devem estar centralizados ao invés de ficarem dispersos por muitas secretarias ou agências, podem ser usados para informação, consulta e participação.

Outra questão temporal a ser considerada diz respeito ao ritmo de processamento das informações recolhidas ao longo dos processos de envolvimento social. Certamente, não convém despender muito tempo desde o fim de uma iniciativa de curto prazo até o processamento final das informações e a tomada de decisão final. Se esse intervalo for muito grande, corre-se o risco de trabalhar com informações que ficaram obsoletas. Porém, conforme apontado por Gusmano[77], existe o período de que as iniciativas de engajamento acabem perturbando a serenidade das agências de avaliação ao iluminar algumas necessidades urgentes sentidas pela população. O risco, aqui, seria a tomada de decisões

pouco refletidas e precipitadas. Assim, é preciso, sim, que as iniciativas suscitem respostas rápidas, mas é também preciso compreender que as informações colhidas em iniciativas de engajamento complexificam o contexto decisório, o que requer algum tempo para o processamento de informação e a produção de relatórios conclusivos.

As diretivas que apresentamos a seguir dizem respeito a iniciativas de curta duração. Porém, é fundamental não esquecer a importância da criação e manutenção de esquemas constantes de informação, consulta e participação.

5.2.2 Preparando um Processo de Participação Social

É ilusório pensar que mecanismos de engajamento (e sobretudo os de participação) podem ser efetivos sem que haja, previamente, a coleta de algumas informações. Conforme explicado por Cyril e colaboradores[39], iniciativas de participação podem falhar se não existir um prévio conhecimento de algumas características das populações e lugares envolvidos. Mais do que isso, é preciso conhecer e considerar:

a. o tipo de tecnologia avaliada
b. a história dessa tecnologia e sua implementação no Brasil
c. dificuldades de uso e acesso dessa tecnologia no Brasil
d. os debates sociais em curso no país acerca dessa tecnologia
e. quais são os grupos mais interessados em discutir a tecnologia
f. quais são as entidades, ONGs, grupos de pacientes, entre outros, que têm ações referentes à tecnologia
g. que tipos de empresas têm ações referentes à tecnologia

É somente com base nessas informações iniciais que uma iniciativa de envolvimento social bem-sucedida pode ser desenhada. Isso é ainda mais crucial nos modelos de participação, em que dilemas, questões, ideias, discordâncias, têm que ser apresentados às pessoas, de modo que elas possam reagir e expressar suas convicções e demandas. Pode-se dizer que toda iniciativa de participação tem por base uma pergunta. Por exemplo: “é necessário incluir certo medicamento na lista de medicamentos essenciais do Ministério da Saúde”? Porém, a questão tem que ser apresentada aos participantes de tal modo que possa captar seu verdadeiro ponto de vista, sem gerar vieses. Muitas vezes, ela não é de fato apresentada sob forma de pergunta direta. Além disso, pode ser formulada de maneiras diferentes conforme o público participante. Por exemplo, a questão em avaliação seria provavelmente apresentada de maneiras diferentes dependendo do grau de conhecimento científico e técnico dos participantes.

5.2.3 Escolhendo a Metodologia de Participação

Em qualquer processo de engajamento social, uma das etapas mais decisivas é a escolha do método a ser utilizado. Basicamente, são duas as decisões principais. Primeiro, é preciso escolher a modalidade de engajamento: informação, consulta ou participação. Segundo, se a participação for a modalidade escolhida, é preciso escolher uma metodologia de engajamento: entrevistas, grupos focais, júris etc. Nossa revisão sistemática mostrou que há dezenas de métodos de participação já executados e registrados em outros países.

A natureza empírica e experimental dos processos de envolvimento se faz mais evidente nesta questão de escolha de modalidades e métodos. Ou seja, é preciso aplicar os modelos e métodos, observar seus resultados, e então avaliar a viabilidade de repeti-los, modificá-los ou abandoná-los no futuro. As diretivas que apresentamos agora são, portanto, um referencial para que se inicie tal processo de experimentação prática.

Tomamos por base a classificação das tecnologias que são geralmente avaliadas pela CONITEC/DGITS/SCTIE/MS. Essa estratégia de exposição tem respaldo na literatura. Num estudo conduzido por Gagnon e colaboradores[68], diretores de hospitais e pacientes declararam que o tipo de participação deve depender do tipo de tecnologia sendo avaliada. Num outro estudo realizado por Gauvin e colaboradores[67], a mesma declaração foi feita por representantes de agências de avaliação de tecnologias.

PROGRAMAS EDUCACIONAIS E INFORMAÇÕES

À primeira vista, pode parecer que, ao falarmos de programas educacionais e informações, estamos tratando apenas de informação (e não de consulta e participação). Isso é compreensível porque, de fato, o componente de informação, neste caso, é bastante importante, já que se trata de disseminar informações precisas, com base em evidências científicas. Portanto, iniciativas clássicas de informação podem ser utilizadas, por meio da internet, rádio, televisão, e outros.

Porém, isso não quer dizer que não caibam aqui iniciativas de consulta e participação. No caso da consulta, ela buscaria avaliar a maneira como as informações têm sido divulgadas. Assim, os cidadãos poderiam expressar opiniões importantes sobre a forma como as informações têm sido assimiladas (ou não têm sido assimiladas) pelo público. Isso é ainda mais importante quando se trata de uma divulgação (publicação e/ou disseminação) nacional, já que as informações podem ter uma recepção diferente em pontos diferentes do país.

No caso da participação, tratar-se-ia de elaborar novas formas de divulgar informações em saúde. Isso é particularmente importante em dois tipos de situação. Primeiro, quando se conclui que as atuais formas de informação têm falhado sucessivamente. Se isso acontece, então os canais utilizados, as formas de informação, as linguagens utilizadas, entre outras coisas, têm que ser repensadas em seu fundamento. É muito importante fazer com que cidadãos participem dessa reflexão, pois são eles mesmos os destinatários da informação. Entrevistas individuais (de preferência presenciais) são uma boa maneira de avaliar essas questões. Elas parecem mais adequadas do que os exercícios coletivos (como os grupos focais) em que a opinião de uma pessoa pode influenciar decisivamente a opinião de outras. Por meio de estratégias individuais, é possível captar mais precisamente os modos como os indivíduos recebem e processam a informação divulgada. No mais, cabe lembrar que, frequentemente, as informações divulgadas são de fato recebidas e processadas individualmente.

EQUIPAMENTOS E PRODUTOS

Estudos demonstraram que, no caso da avaliação de equipamentos e produtos a ser usados pelo paciente, como aparelhos de marcapasso ou próteses, é aconselhável promover a participação de pacientes e médicos em fases iniciais da avaliação, já que eles provavelmente têm conhecimento de equipamentos similares, e sabem quais são as necessidades do uso cotidiano[51,68]. Portanto, a experiência pessoal e profissional é, neste caso, fundamental. Sendo assim, pode-se até pensar numa consulta realizada numa fase inicial do processo, mas a modalidade mais indicada é na verdade a participação propriamente dita. Podem-se convidar pacientes que sejam afiliados a grupos ou instituições dedicadas ao tipo específico de problema de saúde, além de médicos especialistas.

Por outro lado, quando se trata de equipamentos de uso médico e diagnóstico (como os aparelhos de ressonância magnética), o aspecto técnico da questão faz-se muito mais decisivo. Neste caso, uma iniciativa de participação pode ser por demais lenta e custosa. Sendo assim, as consultas parecem mais interessantes. Como o público médico, as entidades e as empresas (agentes mais diretamente envolvidos na questão) representam um público com fácil acesso à internet, então o modelo de consulta online pode render bons resultados. Além disso, considerando-se o aspecto técnico da questão, é possível

pensar numa consulta que mensure dimensões técnicas dos aparelhos, como produtividade, frequência de problemas técnicos, qualidade dos diagnósticos, de modo que os cidadãos consultados possam também fornecer subsídios quantitativos ao processo de avaliação.

PROCEDIMENTOS

Em matéria de procedimentos, os profissionais de saúde são um público particularmente apto a se envolver em projetos de engajamento, sobretudo por conta da experiência prática que possuem. Considerando-se que se trata de um público com acesso relativamente simples à internet, as consultas podem ser uma modalidade bastante útil. Porém, é preciso tomar cuidado para que não apenas os médicos possam contribuir. Outros profissionais, como enfermeiros e assistentes sociais, podem levantar questões igualmente relevantes do ponto de vista do engajamento social.

PROTOCOLOS E DIRETRIZES

A área dos protocolos e diretrizes é talvez aquela que mais se beneficiaria do estabelecimento de iniciativas de participação. Estudos mostraram que as pessoas têm geralmente maior tendência a seguir recomendações quando participam do processo de avaliação da tecnologia[82,12]. Portanto, o estabelecimento de protocolos e procedimentos parece ser uma área importante de participação. Nesse sentido, a participação dos profissionais de saúde, como médicos, enfermeiros e assistentes sociais, parece decisiva. Em grande medida, eles serão os responsáveis pela aplicação dos protocolos e diretrizes. Os métodos coletivos de participação (como os grupos focais ou os júris) parecem bastante adequados, porque, neste caso, é importante que haja troca de opiniões e experiências. Os profissionais de saúde estão geralmente muito imersos em seus contextos de trabalho, incluindo sua cultura de trabalho local, os problemas específicos de seus locais de trabalho, suas relações cotidianas, e assim por diante. Com isso, é importante que estes processos de participação possibilitem uma troca de experiência, de modo a que cada participante possa considerar aspectos que não são facilmente observáveis em seus contextos de trabalho.

Porém, uma dificuldade deve ser considerada. Em métodos coletivos de participação, alguns participantes podem manipular e controlar o processo[65]. Isso acontece quando há pessoas que são mais articuladas ou que, de algum modo, possuem algum tipo de status científico, acadêmico ou profissional superior. Por isso, é fundamental contar com mediadores que saibam conduzir as discussões sem direcioná-las ou enviesá-las. Desse modo, todas as vozes poderão ser ouvidas, mesmo aquelas que ficariam sufocadas no caso de processos mais livres e espontâneos.

MEDICAMENTOS

A área dos medicamentos é sem dúvida a que traz maiores desafios no tocante ao engajamento social. Isso se deve aos seguintes fatores:

a. interesses envolvidos, como os da indústria farmacêutica
b. hierarquias de conhecimento, impedindo, por exemplo, que pacientes e médicos possam trocar opiniões em pé de igualdade
c. existência de aspectos técnicos, farmacológicos e clínicos bastante complexos
d. existência de aspectos econômicos e farmacoeconômicos também complexos
e. a intensidade que pode ser alcançada pelos debates sociais sobre os medicamentos, já que a importância deles é evidente para todos os tipos de cidadãos. Exemplo disso é a crescente judicialização da luta pelo acesso aos medicamentos, o que tem levado centenas de cidadãos a abrir processos contra o Estado, reivindicando a compra pública deste ou daquele medicamento109.
f. a tradicional exclusão do público não-especialista das discussões sobre medicamentos, levando à

formulação de apelos para uma maior participação tanto por parte de organizações de pacientes[110] como por parte de analistas que estudaram a condução de pesquisas clínicas[111,112]

g. existência de várias classes de medicamentos, cada um com suas especificidades

Esse último aspecto, aliás, quase nos permitiria dizer que, ao enfocar os medicamentos, não estamos tratando de uma só área, mas de várias áreas dentro de uma só. Para enfrentar essa complexidade, do ponto de vista da participação social, vamos adotar uma divisão muito simples, considerando a existência de dois tipos de medicamentos: os de uso geral, ou seja, aqueles que se usam no tratamento de doenças de ampla ocorrência, como analgésicos, anti-inflamatórios ou insulina; e os de uso restrito, ou seja, aqueles que se destinam ao tratamento de doenças raras.

Quanto aos medicamentos de uso geral, políticas e iniciativas referentes a eles certamente seriam fortalecidos por meio da participação social. Aqui, cabe o mesmo comentário que fizemos sobre equipamentos e produtos: muitos cidadãos tem um conhecimento empírico, por já ter tido contato com diversos tipo de medicamentos. Porém, é fundamental levar em consideração as assimetrias políticas e cognitivas que hoje existem. Por um lado, alguns agentes sociais, e sobretudo os que representam a indústria farmacêutica, têm vasta experiência no contato com agências decisórias, por meio de conhecimento pessoal e atividades de lobby. Por outro lado, é inegável que a maioria do público não possui o conhecimento científico e técnico necessário para avaliar os medicamentos do ponto de vista farmacológico, biológico e assim por diante. Desse modo, é de se esperar que as iniciativas de participação renderão melhores frutos se os participantes forem separados em grupos de acordo com seu conhecimento científico. Em atividades de que participe o público leigo, parece muito importante, porém, contar com a presença dos membros leigos dos comitês de ética, já que essas pessoas possuem um conhecimento um pouco mais aprofundado dos medicamentos sem porém representar uma autoridade científica intimidante.

Quanto aos medicamentos de uso restrito, para tratamentos de doenças raras, parece mais adequado restringir o escopo das iniciativas de participação. Para a maioria das pessoas, não faria muito sentido participar, por exemplo, de uma discussão sobre medicamentos para doença de Gaucher, um mal que acomete 1 entre 120 mil brasileiros. Porém, para as pessoas com essa doença, bem como seus familiares, tal participação seria provavelmente de grande interesse. As secretarias estaduais de saúde, que fazem a distribuição desses medicamentos pelo SUS, têm o cadastro dos pacientes, que poderiam ser convidados em casos de discussões participativas. Além disso, pessoas com certas doenças têm criado associações de doentes. Por exemplo, para a doença de Crohn, que é um mal de baixa incidência no Brasil, existe a Associação Brasileira de Colite Ulcerativa e Doença de Crohn. Representantes desse tipo de associação também poderiam ser convidados para algumas iniciativas de participação. Obviamente, essas pessoas teriam por prioridade a defesa dos interesses de sua associação e a inclusão, na lista de medicamentos essenciais do Brasil, de mais medicamentos voltados a sua doença. Porém, é preciso fazer duas considerações. Primeiro, nos processos participativos, não é um problema se os participantes têm ideias e agendas predefinidas. O objetivo é, justamente, fazer com que ideias e agendas diversas sejam levadas em consideração e contrastadas com outras agendas e ideais. Segundo, representantes de associações de pacientes podem ter reivindicações que sejam pertinentes não apenas no caso de suas doenças específicas, mas também para diversos outros tipos de doença.

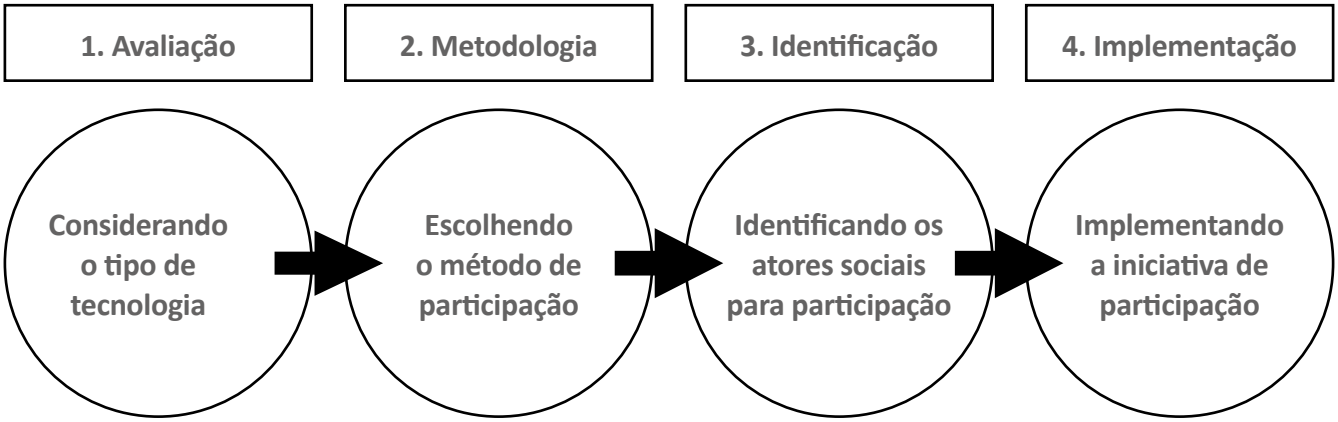
Os medicamentos por vezes são alvos de interesses divergentes. Além disso, o rol de pessoas potencialmente envolvidas costuma ser relativamente grande. Então, parece que as iniciativas de participação, nesse caso, devam envolver um número relativamente grande de pessoas. Métodos como os júris, os fóruns e as audiências parecem adequados, em atividades que podem até se estender

por mais de um dia. Além disso, em discussões amplas tais como as relativas à política nacional de medicamentos, pode-se mesmo pensar em repetir as mesmas estratégias de participação em sequência, em diferentes regiões e cidades brasileiras.

5.2.4 Identificação e Convocação de Participantes

O desenho inicial de uma iniciativa de participação social pode ser ilustrado da seguinte forma na Figura 3:

Figura 3 – Desenhando uma Iniciativa de Participação Social



Conforme a literatura internacional insiste, a etapa número 3 (identificação) é de importância decisiva. Num país como o Brasil, de grandes dimensões, diversidades e desigualdades, ela assume uma relevância ainda maior, pelo risco de que grupos minoritários ou de pouco poder político sejam excluídos do processo. Porém, nem todos os casos vão demandar uma participação realmente ampla, de alcance nacional. Sendo assim, uma boa calibragem das iniciativas deve considerar a existência de quatro níveis, como apresentado no Quadro 1 a seguir:

Quadro 1 – Quadro de Apoio à Tomada de Decisão sobre Modelos de Participação Social em Processos de Avaliação de tecnologias em Saúde e Tomada de Decisão Sobre Cobertura em Quaisquer Níveis de Sistemas de Saúde

		Nível			
		Direcionada	Local	Nacional	Regional
Modelo	Informação	Informação direcionada	Informação local	Informação nacional	Informação regional
	Consulta	Consulta direcionada	Consulta local	Consulta nacional	Consulta regional
	Participação	Participação direcionada	Participação local	Participação nacional	Participação regional

A informação, consulta ou participação será direcionada quando o tema em questão disser respeito, mais diretamente, a um segmento específico da população que esteja espalhado pelo território nacional. Isso pode envolver, por exemplo, um medicamento contra uma doença rara ou um equipamento médico usado por um pequeno número de pacientes. Apesar de o público diretamente interessado estar espalhado pelo território, ele é composto por poucos indivíduos. Quando a inciativa for direcionada,

pessoas mais diretamente envolvidas podem ter prioridade. Segundo O'Doherty e colaboradores[53], quando a deliberação envolve uma questão que afeta um grupo específico, é melhor que os participantes sejam selecionados nesse grupo. Porém, não se podem excluir outras pessoas. Conforme demonstraram Rosenberg-Yunger e Bayoumi[42], o ponto de vista de representantes do público pode ser, de uma forma substancial, diferente do ponto de vista de representantes de pacientes diretamente envolvidos com a questão discutida.

O nível local diz respeito a uma cidade, uma unidade da federação ou uma área que, mesmo que envolvendo duas ou mais unidades da federação, ainda é espacialmente restrita. Na tomada de medidas referentes a esse nível local, os habitantes do lugar são decerto um público preferencial. Porém, deve-se considerar também: os habitantes de locais vizinhos que possam, de algum modo, ser afetados pelo processo deliberativo; os habitantes de outros lugares, próximos ou longínquos, que já tenham alguma experiência nas matérias em questão; e os especialistas nas matérias em questão. Pois, conforme demonstraram Rosenberg-Yunger e Bayoumi[42], o ponto de vista do público pode ser, de uma forma substancial, diferente do ponto de vista dos moradores de uma região diretamente interessada.

O nível regional diz respeito a temas que envolvem duas ou mais unidades da federação. Um exemplo disso foi a recente eclosão de casos de febre amarela, que ameaçou sobretudo os estados da região Sudeste do país, mas sobretudo São Paulo e Minas Gerais. Mais uma vez, moradores dos lugares em questão devem decerto constituir um público prioritário. Porém, é preciso considerar o desenho federativo brasileiro, que por vezes coloca os diversos estados em posições de conflito. Desse modo, é preciso evitar processos deliberativos que sejam excessivamente favoráveis a certos estados, e contrários às prioridades de outros estados.

Finalmente, existe o nível nacional, composto por questões que, potencialmente, dizem respeito à maioria da população brasileira. Um exemplo é a política nacional de medicamentos ou a política nacional de vacinação. Neste caso, a principal preocupação deve ser a consideração das diversidades regionais brasileiras, já que a mesma questão pode ser vista sob diferentes prismas em diferentes estados ou regiões. Em certo sentido, pode-se até considerar que o engajamento (principalmente a consulta e a participação) tem um certo caráter estatístico, cabendo às agências decisórias incluir uma amostra que seja representativa das diversidades geográficas brasileiras. De outro modo, o engajamento pode ter o efeito perverso de impor as preferências de certos lugares a outros lugares.

Assim, uma questão que não deve ser simplesmente ignorada é, por exemplo, a desigualdade de acesso à internet no Brasil. Segundo a Pesquisa Nacional de Amostra por Domicílios do IBGE, publicada em 2018 com dados de 2016, 64,7% dos domicílios brasileiros possuíam acesso à internet. Porém, as regiões Norte e Nordeste ficam abaixo dessa média nacional, com 54,3% e 52,3% de acesso, respectivamente. Sabe-se que, nos últimos anos, mais e mais pessoas têm contribuído para as consultas públicas pela internet. Segundo dados da Comissão Nacional de Incorporação de Tecnologias no SUS, o número de contribuições passou de 1.812 em 2012 para 12.393 em 2015 (Comissão Nacional de Incorporação de Tecnologias no SUS, 2016). Considerando as referidas desigualdades de acesso à internet, esse crescente número de participações em consultas pode estar levando a uma super-representação dos lugares, estados e regiões onde o acesso à internet está mais difundido. Temos aqui, portanto, mais uma razão para aperfeiçoar os esquemas de engajamento brasileiros, fazendo-os ir além das consultas públicas.

Em se tratando de iniciativas propriamente participativas, cabe imaginar a existência de duas formas de inclusão. Primeiro, atores sociais com interesse no assunto (como especialistas, profissionais de saúde ou representantes de associações de pacientes) podem ser convidadas. Segundo, pode ser divulgada a

organização de uma iniciativa futura, e então as pessoas se inscreveriam como voluntárias. Essa segunda forma é relatada no texto de Fitzgerald e colaboradores[85] e se mostrou particularmente bem-sucedida no recrutamento de indivíduos realmente motivados a participar.

É possível que, conforme as iniciativas de participação forem se repetindo e consolidando, alguns indivíduos se mostrem dispostos a colaborar com frequência. Segundo Sykes e Goodwin[96], treinamento pode inclusive ser oferecido a esses participantes mais frequentes. Porém, a questão levantada por Abelson e colaboradores[65] é muito importante: se alguns participantes estão presentes em várias iniciativas, isso pode gerar fadiga e um consequentemente baixo envolvimento.

5.2.5 Analisando os Resultados

Por mais rico e bem-estruturado que possa ser uma iniciativa de engajamento, pouco proveito poderá ser extraído se não houver, posteriormente, uma atenta e detalhada análise das informações colhidas durante o processo. Do ponto de vista da agência que promove a iniciativa, o resultado será sempre esse: a coleta de informações, que devem trazer novos subsídios à deliberação em curso. Para que tal análise seja realizada, é preciso contar com pessoal capaz de processar alguns dados quantitativos. Porém, o maior desafio é realizar uma adequada análise qualitativa, pois, durante os processos de engajamento, são coletados discursos, opiniões, interesses, argumentos. Assim, o desafio é entender como todas essas ideias se entrelaçam, formando uma teia ideológica na qual se amarra a tecnologia em discussão. Trata-se, também, de uma análise política, pois certas tecnologias, quando adotadas, promovidas e disseminadas de um certo modo, podem ser mais favoráveis a certos grupos sociais do que outros. Em teoria, faz-se praticamente impossível adotar e implementar tecnologias de modo tal que todos os diferentes grupos sociais sejam favorecidos ou frustrados. Por isso, é preciso que as agências governamentais saibam também compreender as implicações políticas e sociais de suas decisões, minimizando eventuais perdas drásticas que alguns grupos possam experienciar.

Na análise de informações provenientes de processos de engajamento, é preciso que três ideias sejam sempre levadas em consideração. Primeiro, é pouco realista esperar que, em todos os casos, o processo de engajamento vá levar a consensos. Nem se pode pretender que, ao reunir diferentes agentes sociais para debater uma tecnologia ou um procedimento, seja sempre possível chegar a um acordo final. Conforme apontaram Deng e Wu[31], debates sobre tecnologias médicas nem sempre geram consensos. E de acordo com Boivin e colaboradores[38], atividades que têm por objetivo a geração de um consenso podem resultar muito longas. Sendo assim, é importante considerar que, em iniciativas de engajamento (e sobretudo quando a modalidade escolhida for a participação), o consenso não deve ser forçado. Por vezes, a tensão e a discordância podem ser mais interessantes do ponto de vista da agência que promove a iniciativa, porque, desse jeito, ficam evidentes quais são os conflitos a redor da tecnologia em questão. Nesses casos, a iniciativa de engajamento vai, primordialmente, identificar quais são os interesses conflitantes e como eles poderão ser balanceados.

Segundo, a avaliação das tecnologias deve ser feita sob a luz de evidências científicas. Porém, quando se trata de realizar iniciativas de engajamento, não se pode estar disposto a escutar, apenas, o que dizem os cientistas e os especialistas. Whitty[11] nos adverte que pode haver discordâncias entre o que dizem os cientistas e o que é esperado pelo público leigo. Um exemplo bastante claro é o recente caso da fosfoetanolamina, em que as evidências científicas desabonam e eficácia terapêutica da “pílula do câncer”, mas, mesmo assim, alguns pacientes insistem em buscar acesso ao composto. Do ponto de vista das agências promotoras de iniciativas de engajamento, uma atitude de abertura será sempre benéfica, pois, de outro modo, bastaria ouvir apenas o que dizem os cientistas. Ainda que o público leigo tenha expectativas e sugestões discordantes em relação ao discurso científico oficial, é importante

levar em consideração essas visões, pois, de outro modo, é possível, por exemplo, que certas políticas sanitárias tenham pouca adesão por parte do público, o qual pode não reconhecer sua legitimidade e coerência. No mais, vale lembrar que as evidências científicas não são verdades reveladas: muitas vezes, elas são produzidas por empresas e instituições que buscam, primordialmente, a melhoria de sua condição institucional ou econômica. Nesse sentido, há uma vasta literatura mostrando como, por exemplo, as evidências farmacológicas são frutos de pesquisas clínicas meticulosamente arranjadas ou mesmo manipuladas por grandes corporações farmacêuticas[111, 113-115]. Finalmente, não é interessante esperar que, ao longo de um processo de engajamento, instruções e sugestões precisas sejam sempre expressadas pelo público. Conforme lembrado por Oliver e colaboradores[44],pontos de vista apresentados por cidadãos podem ser bem amplos e até mesmo vagos. Portanto, cabe à agência que promove o engajamento chegar ao nível de especificidade necessário para a tomada de decisões. Como as informações colhidas são de natureza política e não técnica, de natureza primordialmente qualitativa e não quantitativa, então um entendimento final seja será, muitas vezes, fruto da análise.

Atualmente, existem técnicas disponíveis que permitem o processamento quantitativo de informações qualitativas. Por exemplo, há softwares e pacotes computacionais que introduziram técnicas como mineração de texto e contagem de expressões. Se utilizados com parcimônia, tais técnicas podem ser úteis. Porém, conforme já afirmamos, iniciativas de engajamento geram, primordialmente, informações qualitativas que devem ser tratadas por meio de enfoques como a análise de discurso, a identificação de ideologias políticas, a consideração de fatores culturais, e assim por diante. Sem dúvida, um processo de engajamento pode levar a recomendações específicas e precisas, e este é um objetivo central. Porém, antes de chegar a tais recomendações, é preciso abrir espaço a um processo de análise que não seja estritamente dependente de parâmetros quantitativos e técnicos.

5.2.6 Registrando o Processo

Perfetto e colaboradores[78], ao estudar processos participativos, apontaram a possibilidade de uma participação indireta. Isso acontece quando a agência promotora leva em consideração informações e registros escritos referentes à visão dos cidadãos sobre certas tecnologias. De modo a promover a participação indireta, qualquer tipo de processo de engajamento deve ser registrado com cuidado, pois isso vai gerar um arquivo que pode ser bastante útil no futuro. Com base nesses registros, será possível saber, futuramente, quais métodos de engajamento são mais adequados para cada tipo de discussão. Além disso, será possível avaliar como evoluem os anseios dos cidadãos em relação a certas tecnologias. Finalmente, o registro dos processos de engajamento é fundamental para que exista transparência sobre os passos que estão sendo tomados pelas agências de avaliação. Abelson e colaboradores[66] ressaltam a importância de publicar todo o processo de participação.

5.2.7 A Infraestrutura da Participação Social

A leitura das seções anteriores já deve ter deixado clara uma ideia crucial: a elaboração, realização e processamento de processos de engajamento (e sobretudo de participação) não podem acontecer sem que haja uma infraestrutura adequada. Essa infraestrutura envolve, certamente, a existência de recursos informacionais como computadores, acesso à internet e pacotes (gratuitos e livres) de análise de discurso. Pesquisadores já argumentaram que processos participativos requerem a reserva de recursos materiais e econômicos[12].

Porém, o principal fator é o recurso humano, correspondente a uma equipe responsável pelos processos de engajamento, conforme já lembravam Moran e Davidson[46]. Várias tarefas seriam realizadas por essa equipe, por exemplo:

a. discutir, com as agências promotoras, os objetivos e o formato do processo de engajamento
b. coleta de informações anteriormente ao processo de engajamento, consultando jornais, sites e blogs, por exemplo

c. identificação e recrutamento de participantes, como no exemplo oferecido por Kashefi e Mort[116],bem como no exemplo oferecido por Gagnon e colaboradores[32]
d. processamento das informações obtidas ao longo do processo
e. manutenção dos arquivos com as informações de processos já realizados
f. manutenção de canais de diálogo com o público

Essas e outras tarefas seriam mais adequadamente realizadas se ficassem a cargo de uma equipe especializada. Isso é importante se o objetivo for a implementação de processos que realmente capturem toda a riqueza do debate social, e não apenas a instalação de mecanismos burocráticos que visem, tão-somente, sinalizar uma preocupação social por parte das agências. Por fim, a existência de uma equipe especializada e multidisciplinar é importante para que, por fim, iniciativas de participação possam fazer parte da realidade administrativa brasileira, indo além da simples informação e consulta.

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7. Anexos

Anexo 1 – Estratégias de Busca Bases de Dados Eletrônicas

Base de dados	Estratégia	Resultados
Pubmed #10	((((("Patient Participation"[Mesh] OR Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR "Community Participation"[Mesh] OR Public Participation OR "Social Participation"[Mesh] OR social participation OR citizen participation OR citizen OR public consultation)) AND ((("Decision Making"[Mesh] OR Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy)) OR (funding [Title/Abstract] OR coverage [Title/Abstract] OR "priority setting" [Title/Abstract] OR "resource allocation" [Title/Abstract] OR reimburs* [Title/Abstract] OR investment [Title/Abstract] OR procurement [Title/Abstract] OR disinvest* [Title/Abstract] OR reinvest* [Title/Abstract] OR reallocation [Title/Abstract] OR defunding [Title/Abstract] OR delisting [Title/Abstract] OR delist* [Title/Abstract] OR dis-invest* [Title/Abstract] OR withdraw* [Title/Abstract] OR de-adopt* [Title/Abstract] OR deadopt* [Title/Abstract] OR divest* [Title/Abstract] OR decommission* [Title/Abstract] OR de-fund*[Title/Abstract] OR "low-value" [Title/Abstract] OR "low value"[Title/Abstract]))))) AND ((“Technology Assessment, Biomedical"[Mesh] OR health technology assessment OR health technology OR technology biomedical OR HTA))	1215
Open Grey	(Patient Participation OR Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR Community Participation OR Public Participation OR Social Participation OR social participation OR citizen participation OR citizen OR public consultation) AND (Decision Making OR Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy) AND (Technology	

Base de dados	Estratégia	Resultados
	Assessment, Biomedical OR health technology assessment OR health technology OR technology biomedical OR HTA)	
CINAHL #2	(TX Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR Community Participation OR Public Participation OR Social Participation OR citizen participation OR citizen OR public consultation) AND (SU Decision Making OR Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy) OR (AB funding OR coverage OR "priority setting" OR "resource allocation" OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR dis-invest* OR withdraw* OR de-adopt* OR deadopt* OR divest* OR decommission* OR de-fund* OR "low-value" OR "low value OR (TI funding OR coverage OR "priority setting" OR "resource allocation" OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR dis-invest* OR withdraw* OR de-adopt* OR deadopt* OR divest* OR decommission* OR de-fund* OR "low-value" OR "low value) AND (TX health technology assessment OR health technology OR HTA OR Technology Assessment Biomedical OR technology biomedical)	492
Cochrane Library #2	#1 MeSH descriptor: [Patient Participation] explode all trees : 1138 #2 Participation Patient or Patient Involvement or Patient Engagement or Patient empowerment or Community Participation or Public Participation or Social Participation or social participation or citizen participation or citizen or public consultation or consultation:ti,ab,kw (Word variations have been searched) : 24051 #3 MeSH descriptor: [Community Participation] explode all trees : 1334	140

Base de dados	Estratégia	Resultados
	#4 MeSH descriptor: [Social Participation] explode all trees : 60 #5 MeSH descriptor: [Decision Making] explode all trees : 3683 #6 Decision-Making or decision making or Militancy or Lobby or Advocacy:ti,ab,kw (Word variations have been searched) : 10914 #7 Funding or coverage or "priority setting" or "resource allocation" or reimburs* or investment or procurement or disinvest* or reinvest* or reallocation or defunding or delist* or dis-invest* or withdraw* or de-adopt* or deadopt* or divest* or decommission* or de-fund* or "low-value" or "low value":ti,ab,kw (Word variations have been searched) : 40782 #8 MeSH descriptor: [Technology Assessment, Biomedical] explode all trees : 638 #9 technology assessment or health technology or HTA or technology biomedical:ti,ab,kw (Word variations have been searched) : 6060 #10 = #1 or #2 or #3 or #4 : 24063 #11 = #5 or #6 or #7 : 52165 #12 = #8 or #9 : 6064 #13 = #10 and #11 and #12 : 140	
CRD #1	#1 MeSH DESCRIPTOR Patient Participation EXPLODE ALL TREES #2 MeSH DESCRIPTOR Community Participation EXPLODE ALL TREES #3 MeSH DESCRIPTOR Social Participation EXPLODE ALL TREES #4 (Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR Public Participation OR social participation OR citizen participation OR citizen OR public	21

Base de dados	Estratégia	Resultados
	consultation) #5 MeSH DESCRIPTOR Decision Making EXPLODE ALL TREES #6 (Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy) #7 (funding OR coverage OR "priority setting" OR "resource allocation" OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR dis-invest* OR withdraw* OR de-adopt* OR deadopt* OR divest* OR decommission* OR de-fund* OR "low-value" OR "low value") #8 MeSH DESCRIPTOR Technology Assessment, Biomedical EXPLODE ALL TREES #9 (health technology assessment OR health technology OR technology biomedical OR HTA) #10 = #1 OR #2 OR #3 OR #4 #11 = #5 OR #6 OR #7 #12 = #8 OR #9 #13 = #10 AND #11 AND #12	
Embase #3	'patient participation'/exp OR 'patient participation' OR ('community participation'/exp AND [embase]/lim) OR ('social participation'/exp AND [embase]/lim) OR (participation AND patient OR patient AND involvement OR patient AND engagement OR patient AND empowerment OR community AND participation OR public AND participation OR social AND participation OR social AND participation OR citizen AND participation OR citizen OR public AND consultation OR consultation AND [embase]/lim) AND ('decision making'/exp OR 'decision making' AND [embase]/lim OR ('decision making' OR decision AND making OR militancy OR lobby OR advocacy AND [embase]/lim) OR (funding	917

Base de dados	Estratégia	Resultados
	OR coverage OR 'priority setting' OR 'resource allocation' OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR 'disinvest*' OR withdraw* OR 'de adopt*' OR deadopt* OR divest* OR decommission* OR 'de fund*' OR 'low-value' OR 'low value' AND [embase]/lim)) AND ('biomedical technology assessment'/exp OR 'biomedical technology assessment' AND [embase]/lim OR (health AND technology AND assessment OR health AND technology OR hta AND embase]/lim))	
EPISTEMONIKOS #3	(advanced_title_en:(Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR Public Participation OR social participation OR citizen participation OR citizen OR public consultation) OR advanced_abstract_en:(Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment OR Public Participation OR social participation OR citizen participation OR citizen OR public consultation)) AND (advanced_title_en:(Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy OR coverage OR resource allocation OR reallocation OR defunding) OR advanced_abstract_en:(Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy OR coverage OR resource allocation OR reallocation OR defunding)) OR (advanced_title_en:(health technology assessment OR health technology OR technology biomedical OR HTA) OR advanced_abstract_en:(health technology assessment OR health technology OR technology biomedical OR HTA)) [Filters: protocol=no]	133
Health Systems Evidence	(Participation Patient OR Public participation) AND ("health technology assessment") AND (Decision-Making OR decision making)	35
LILACS #2	tw:((participação da comunidade OR participação de paciente OR opinião pública)(avaliação de	5

Base de dados	Estratégia	Resultados
	tecnologia em saúde OR avaliação da tecnologia biomédica OR tecnologia em saúde OR tecnologia biomédica)) AND (instance:"regional") AND (db:("LILACS"))	
PDQ #1	(title:(Participation Patient) OR abstract:(Participation Patient)) OR (title:(Community Participation) OR abstract:(Community Participation)) OR (title:(Public Participation) OR abstract:(Public Participation)) OR (title:(Social Participation) OR abstract:(Social Participation)) OR (title:(citizen) OR abstract:(citizen)) OR (title:(Patient Engagement) OR abstract:(Patient Engagement)) AND (title:(Decision Making) OR abstract:(Decision Making)) OR (title:(Militancy) OR abstract:(Militancy)) OR (title:(Advocacy) OR abstract:(Advocacy)) OR (title:(funding OR coverage) OR abstract:(funding OR coverage)) OR (title:(resource allocation) OR abstract:(resource allocation)) OR (title:(reallocation OR defunding) OR abstract:(reallocation OR defunding)) OR (title:(health technology assessment) OR abstract:(health technology assessment)) OR (title:(health technology) OR abstract:(health technology)) OR (title:(Technology Assessment Biomedical) OR abstract:(Technology Assessment Biomedical)) OR (title:(technology biomedical) OR abstract:(technology biomedical)) OR (title:(HTA) OR abstract:(HTA))	175
PSYCINFO #1	(((Abstract : (funding OR coverage OR " priority setting" OR " resource allocation" OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR disinvest* OR withdraw* OR deadopt* OR deadopt* OR divest* OR decommission* OR defund* OR " lowvalue" OR " low value"))) OR ((Subject : (Decision Making) OR Subject : (DecisionMaking) OR Subject : (decision making) OR Subject : (Militancy) OR Subject : (Lobby) OR Subject : (Advocacy)))) *AND* ((Any Field : (health technology assessment) *OR* Any Field : (health technology) *OR* Any	270

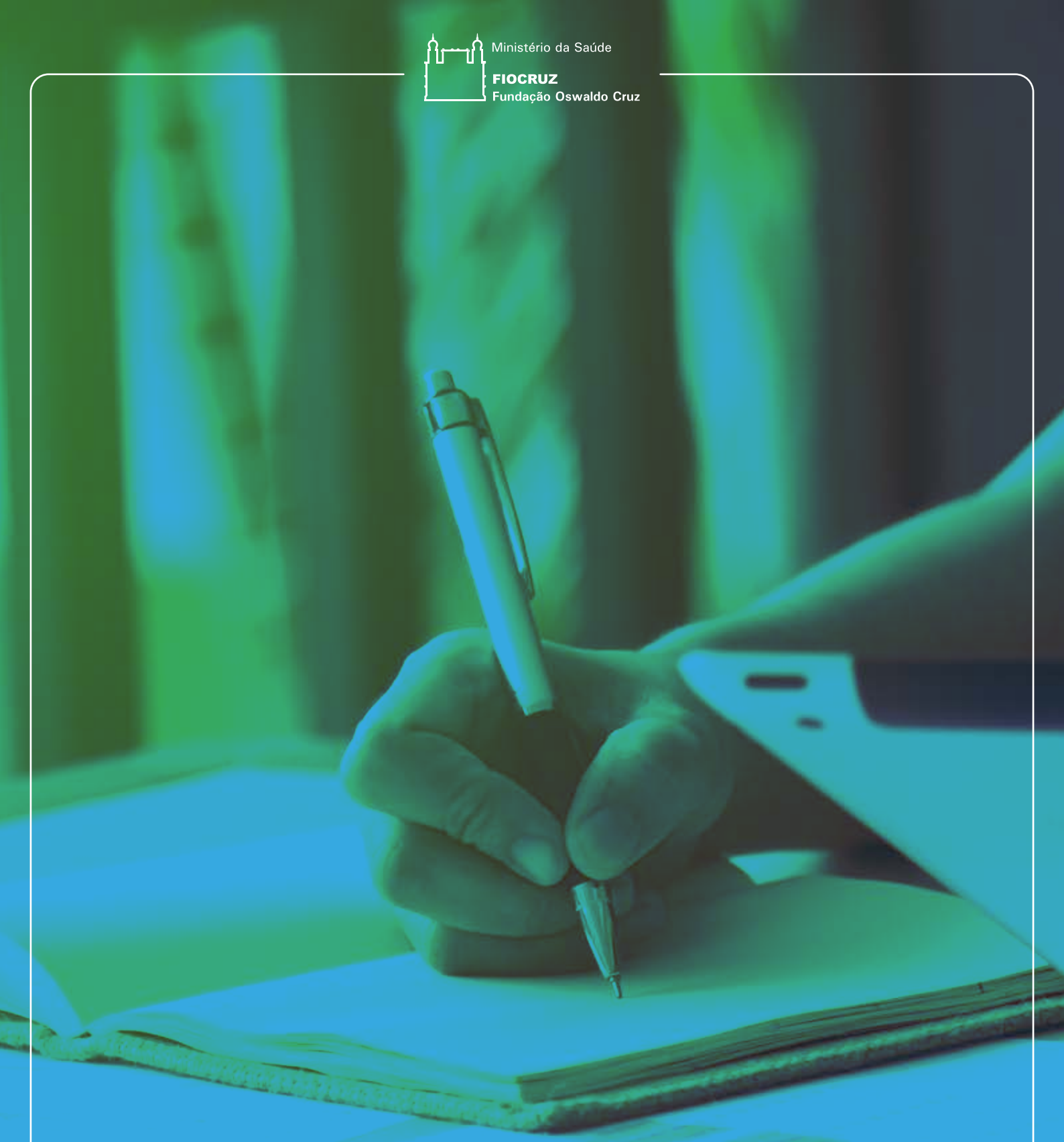
Base de dados	Estratégia	Resultados
	Field : (HTA) *OR* Any Field : (Technology Assessment Biomedical) *OR* Any Field : (technology biomedical))) *AND* ((Any Field : (Participation Patient) *OR* Any Field : (Patient Involvement) *OR* Any Field : (Patient Engagement) *OR* Any Field : (Patient empowerment)) *OR* (Any Field : (Community Participation) *OR* Any Field : (Public Participation) *OR* Any Field : (Social Participation) *OR* Any Field : (social participation) *OR* Any Field : (citizen participation) *OR* Any Field : (citizen) *OR* Any Field : (public consultation)))	
Scopus #1	((TITLE-ABS-KEY (participation AND patient OR patient AND involvement OR patient AND engagement OR patient AND empowerment) OR TITLE-ABS-KEY (community AND participation OR public AND participation OR social AND participation OR social AND participation OR citizen AND participation OR citizen OR public AND consultation))) AND ((TITLE-ABS-KEY (decision AND making OR decision-making OR decision AND making OR militancy OR lobby OR advocacy)) OR (TITLE-ABS-KEY (health AND technology AND assessment OR health AND technology OR hta OR technology AND assessment AND biomedical OR technology AND biomedical)))	655
Web of Science #1	# 1 **168.727** **TS=** (Participation Patient OR Patient Involvement OR Patient Engagement OR Patient empowerment) *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 2 **137.572** **TS=** (Community Participation OR Public Participation OR Social Participation OR social participation	579

Base de dados	Estratégia	Resultados
	OR citizen participation OR citizen OR public consultation) *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 3 **398.599** **TS=** (Decision Making OR Decision-Making OR decision making OR Militancy OR Lobby OR Advocacy) *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 4 **158.117** TI=(funding OR coverage OR "priority setting" OR "resource allocation" OR reimburs* OR investment OR procurement OR disinvest* OR reinvest* OR reallocation OR defunding OR delist* OR dis-invest* OR withdraw* OR de-adopt* OR deadopt* OR divest* OR decommission* OR de-fund* OR "low-value" OR "low value") *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 5 **68.694** TS=(health technology assessment OR health technology OR HTA OR Technology Assessment Biomedical OR technology biomedical) *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 6 **298.820**	

Base de dados	Estratégia	Resultados
	#2 OR #1 *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 7 **551.037** #4 OR #3 *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos* # 8 **579** #7 AND #6 AND #5 *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos*	
Total		4.637
Duplicatas		688
Total Mendeley **(**- Duplicatas)		3.949

Anexo 2 – Tabela Resumo Avaliação AMSTAR 2 das Revisões Sistemáticas Incluídas nesta Síntese de Evidências Qualitativas

Referência	Sim	Não	Possivelmente Sim	Não-metanálise	GRADE
91	5	5	3	3	Baixo
28	9	2	1	3	Moderado
59	4	8	1	3	Criticamente baixo
60	8	4	1	3	Moderado
67	15	1	0	0	Alto
49	1	12	0	3	Criticamente baixo
40	2	9	2	3	Criticamente baixo
51	4	5	4	3	Baixo
15	8	4	1	3	Moderado
9	13	1	2	0	Alto



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