**Appendix 3: extracted information**

Table 1. General

| Study ID | **Title** | **Objective of HTA** | **Intervention description** | **Country of origin** | **Review planning information** | **Development of a framework** | **Population included** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 | Falls prevention for the elderly | Assess effectiveness of prevention interventions to reduce falls or fall-related injuries in home or institutional environments | Individually tailored preventive measures that are medical or non medical and multimodal or multifactorial prevention programmes | Germany | NR | No | People over 60 years who live in their own houses or in any form of care institutions |
| Fröschl 2013 | Prevention of Fetal Alcohol Syndrome | To assess the effectiveness, cost-effectiveness and ethical, social and legal aspects of preventive interventions for pregnant women and women at childbearing age with risky alcohol consumption patterns to prevent fetal alcohol syndrome (FAS) | Any form of prevention intervention directed at women at childbearing age (e.g. short intervention by gynecologist or midwife, motivational discussion, self-help group) | Germany | NR | No | Women at childbearing age and pregnant women |
| Korzcak 2012 | Efficacy and efficiency of psychological, psychiatric, sociomedical and complementary medical interventions for excessive crying in primary care services ("Schreiambulanzen") | To assess the effectiveness and efficacy of interventions to reduce colic (excessive crying) in babies | different psychological, psychotherapeutic, socio-medical,and complementary medicine interventions | Germany | NR | They adapted a framework developed by Ziegler et al. to show how crying leads to a cascade of negative consequences (poor parental competence, decrease in intuitive support) that perpetuate or accentuate (negligence, abuse) the effects. However, the authors of the HTA do not connect the framework with their research aim, e.g. showing where different interventions could intervene in the problem. | No information, only babies with colic (dt: Schreibabys), with a minimum of 30 cases per study |
| HIQA 2014 | HTA of Public Access Defibrillation | - To review the clinical evidence on the effectiveness and safety of public access defibrillation programmes for out-of-hospital cardiac arrest and identify the main factors associated with effective implementation of such programmes. - To review and summarise Irish data on the epidemiology of out-of-hospital cardiac arrest, the existing availability of automatic external defibrillators, and relevant initiatives in the management of sudden cardiac arrest and the configuration of emergency medical services. - To review the international cost-effectiveness literature on public access defibrillation. - To estimate the clinical benefits, cost-effectiveness, resource implications and budget impact of potential public access defibrillation programme configurations in Ireland. - To consider any wider implications that the technology may have for patients, the general public or the healthcare system. - Based on this assessment, to advise on the optimal configuration of an Irish public access defibrillation programme. | Public access defibrillation interventions that include the provision of static automated external defibrillators (AEDs) in a range of publicly- accessible locations, that are designed to be used opportunistically by trained or untrained volunteers or bystanders who witness a cardiac arrest are eligible for inclusion. Also eligible are studies that involve community groups of trained lay-volunteers or lay responders such as police and firefighters who would not ordinarily have access to AEDs. Interventions that focus on the provision of AEDs in the homes of individuals who are at high risk of cardiac arrest or in hospital or other high dependency care facilities are ineligible | Ireland | “On 25 July 2013, the then Minister for Health, Dr James Reilly, requested that the Health Information and Quality Authority undertake a health technology assessment (HTA) of a public access defibrillation programme. This was with the aim of informing decision-making on matters related to the Public Health (Availability of Defibrillators) Bill 2013.” (p.9)  “The Terms of Reference of the HTA were agreed between the Authority and the Department of Health. An Expert Advisory Group (EAG) was established. An evaluation team was appointed comprising internal Authority staff. Dr Deirdre Madden, Faculty of Law, University College Cork, prepared the ethical and legal analysis. The Health Intelligence Unit in the Health Service Executive (HSE) assisted with the analysis of out-of-hospital cardiac arrest incidence data used in the economic model.” (p.10) | No | All adults and children who experience a sudden cardiac arrest in any location except for hospitals or other high dependency care facilities that monitor patients and routinely provide emergency medical care. This includes sporting and entertainment venues, public areas, commercial premises, long-term care facilities and public transportation services and facilities. |
| Tice 2016 | Diabetes Prevention Programs: Effectiveness and Value | This report addresses several key issues related to DPPs for patients, provider organizations, payers, and other policymakers and includes: 1) a landscape analysis of available DPP approaches; 2) a comparative effectiveness evaluation of DPPs; and 3) an assessment of the costs, cost-effectiveness, and potential budget impact of DPPs. | The interventions of interest included lifestyle interventions to prevent or delay the development of type 2 diabetes mellitus (DM) that have full or pending recognition from the CDC Diabetes Prevention Recognition Program (DPRP), including programs incorporating smartphone and web-assisted delivery methods. Medical and surgical therapies were not considered. ICER previously reviewed the evidence on the clinical effectiveness and value of multiple drug, device, and surgical approaches to weight loss, an outcome that is frequently used as a surrogate for diabetes prevention or delay, in a July 2015 report for CTAF.55 | USA | NR | Analytic Framework (basic PICO/LM mix); care value framework | The population of focus for the review was adults ages 18 and older with prediabetes. We attempted to examine the impact of different definitions of prediabetes on the outcomes of interest, but there was insufficient data to perform this analysis. |
| Bee 2014 | The clinical effectiveness, cost-effectiveness and acceptability of community-based interventions aimed at improving or maintaining quality of life in children of parents with serious mental illness: a systematic review | to assess the clinical effectiveness,cost-effectiveness and acceptability of community-based interventions aimed at increasing or maintaining quality of life (QoL) in children of parents with serious mental illness (SMI). | any community-based (i.e. non-residential) psychological or psychosocial intervention that involved professionals or paraprofessionals and parents or children, for the purposes of changing knowledge, attitudes, beliefs, emotions, skills or behaviours concerning health and well-being. This included any health, social-care or educational intervention aimed at the young person, their parent or their family unit. Interventions that targeted children in the community were eligible for inclusion irrespective of their parents’ inpatient or outpatient status | UK | Within the current review, three separate consultation exercises were undertaken. The ﬁrst involved a mix of clinical academics (with backgrounds in mental health, child psychiatry and clinical psychology) in conjunction with professionals recruited from health- and social-care services, voluntary user-led organisations and national children’s trusts. The second and third consultations were undertaken with individuals with potentially lower inﬂuence yet higher stakes, in this case parents and the children of parents with SMI. […]  Stakeholder consultation took place early in the study to assist the research team in developing an outcome framework for evidence synthesis. Stakeholders also contributed to literature searching (see Chapter 3) and came together in a ﬁnal meeting to assist in framing the presentation of our synthesis results | In order to explore the clinical effectiveness and cost-effectiveness of community-based interventions in enhancing the QoL of children of parents with SMI, we ﬁrst sought to develop a conceptual model of HRQoL in this population | Children aged 0 to < 18 years or their parents, one or more parents with SMI with or without substance misuse/other mental health comorbidity, > 50% sample participants experiencing parental SMI |
| Tappenden 2012 | The clinical effectiveness and cost-effectiveness of home-based, nurse-led health promotion for older people: a systematic review | To assess the clinical effectiveness and cost-effectiveness of home-based, nurse-led health promotion intervention for older people in the UK  ■ review existing health economic evaluations of home-based, nurse-led health promotion programmes from the perspective of the NHS and Personal Social Services (PSS) ■ explore, as far as existing evidence allows, those elements of this form of complex intervention that may contribute to its clinical effectiveness, and ■ identify key gaps in current evidence and to identify areas in which future research may be warranted. | - Structured home-based, nurse-led health promotion  - complex intervention, in that it that may comprise multiple, potentially interacting components. The focus within this assessment is principally on nurse-led health promotion activities undertaken within the subject’s home | UK | NR | No | older people (> 75 years or > 70 years when considered a vulnerable population on the basis of age) with long-term medical or social needs at risk of admission to hospital, residential or nursing care. |
| Brown 2016 | Community pharmacy interventions for public health priorities: a systematic review of community pharmacy-delivered smoking, alcohol and weight management interventions | - To systematically review the effectiveness of community pharmacy interventions to manage alcohol misuse, smoking cessation and weight loss;  - to explore if and how age, sex, ethnicity and socioeconomic status moderate effectiveness; and  - to describe how the interventions have been organised, implemented and delivered. | Any type of community pharmacy intervention to manage alcohol misuse, smoking cessation and weight loss of any duration based in any country and in people of any age was included. | UK | NR | Not developed but usage: The Behaviour Change Wheel32 and the Nuffield Intervention Ladder33 were chosen to broadly describe the interventions by grouping and classifying the policy categories and intervention functions. | people of any age |
| O’Mara-Eves 2013 | Community engagement to reduce inequalities in health: a systematic review, meta-analysis and economic analysis | The overarching aims of this project were to identify community engagement approaches that are effective in improving the health of disadvantaged populations and/or reducing inequalities in health; and to describe the approaches in terms of the circumstances in which they work and the costs associated with their implementation. | community engagement approaches to reduce inequalities of health | UK | User involvement was integrated throughout the project. An advisory group was consulted regarding the review’s conceptual framework and analytical strategies, and they suggested potentially useful research to include in syntheses. Local young people’s advocacy groups were consulted for their perspectives on barriers to and facilitators of community engagement for health inequalities.“  „The project advisory group provided feedback on the research in the project. The advisory group includes public health policy and practitioner members. We had regular informal contact with members of the group by e-mail and telephone, and a formal face-to-face (with some attending by teleconference) meeting to discuss the review’s conceptual framework and analytical strategies | This is one research question of the HTA: to identify theories of change and identify mechanisms how the interventions work:   Data were described and synthesised in a map of the evaluative and theoretical literature that describes the scale and range of community engagement interventions. | Group of people defined as a “community” |
| Bambra 2015 | How effective are interventions at reducing socioeconomic inequalities in obesity among children and adults? Two systematic reviews | To systematically review the effectiveness of interventions (individual, community and societal) in reducing socioeconomic inequalities in obesity among (1) children aged 0–18 years (including prenatal) and (2) adults aged ≥18 years, in any setting, in any country, and (3) to establish how such interventions are organised, implemented and delivered. | Intervention on individual, community and societal levels that might reduce existing inequalities in the prevalence of obesity (i.e. effective targeted interventions or universal interventions that work more effectively in low-SES groups), as well as those interventions that might prevent the development of inequalities in obesity (i.e. universal interventions that work equally along the SES gradient) | UK | NR | To support the conduct of the reviews we developed a novel framework for how inequalities in obesity might be tackled (Table 1). This shows that interventions are characterised by their level of action and their approach to tackling inequalities”. This is a theoretical model adapted from the health inequalities literature. | - Children aged 1-18 yrs (including prenatal) and adults >18 (i.e. two separate reviews per population) - targeted at disadvantaged individuals, communities or society or aimed at reducing childhood obesity universally but analysed and presented the effects of the intervention by SES |

Table 2. Health effectiveness (1)

| **Study ID** | **Synthesis method** | **Number of included studies** | **Included study designs** | **Search strategy: number of databases** | **Handsearches** | **grey literature** | **conference abstracts** | **other** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 | systematic review | 116 | RCTs | 3 | no | no | no |  |
| Fröschl 2013 | systematic review | 10 | RCTs CCTs cohort studies | 30 | no | no | no |  |
| Korzcak 2012 | systematic review | 18 | HTA reports systematic reviews / MAs RCTS cohort studies case-control studies | 32 | yes | no | no |  |
| HIQA 2014 | systematic review | 15 | RCTs NRCTs CBA ITS retrospective observational studies (cohort/cross-sectional/case-control) with a comparison group | 9 | no | no | no |  |
| Tice 2016 | systematic review (update) | 8 | not specified, probably no limitation: they report  RCTs comparative cohort studies case series | 3 | yes |  |  | contacted the CDC and known organizations |
| Bee 2014 | systematic review | 11 | RCTs quasi-RCTs controlled observational studies (e.g. case-control) Uncontrolled studies retained and summarised | 23 | yes | yes | yes | stakeholder consultation, theses |
| Tappenden 2012 | systematic review | 11 | RCTs | 11 | yes (SRs) | no | no | no |
| Brown 2016 | systematic review | 24 | RCTs NRCTs CBAs ITS RM studies | 9 | yes | yes | no | contacting experts, commissioners & providers of such services, |
| O’Mara-Eves 2013 | systematic review + post-hoc narrowing of scope | 319 --> 161 after rescoping, 131 included in MA | no limitation | 9 | yes | partly (HTA website) | no | key contacts were consulted |
| Bambra 2015 | systematic review | for different questions: 76 (children) & 103 (adults) | RCTS NRCTs cohort studies with or without control groups repeat cross-sectional studies with or without control groups | 10 | yes | yes | yes |  |

Table 2. Health effectiveness (2)

| **Study ID** | **single or duplicate study selection** | **single or duplicate data extraction** | **RoB assessment tool** | **single or duplicate RoB assessment** | **Consideration of context/setting?** | **Tool** | **applicability/generalizability** | **Tool** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 | ? | duplicate | Cochrane RoB tool | duplicate | no | - | no | - |
| Fröschl 2013 | NR | ? | own developed RoB tool | NR | no | - | no | - |
| Korzcak 2012 | duplicate | duplicate | Oxford Centre of Evidence-based Medicine: Levels of Evidence | NR | no | - | no | - |
| HIQA 2014 | duplicate | duplicate | EPPHPP Quality Assessment Tool for Quantitative Studies | duplicate | no | - | yes | chapter on applicability of results on Irish context, applicability of other studies, narrative assessment of applicability according to PICOs |
| Tice 2016 | single | NR but very likely single | criteria published by the USPSTF | NR, probably single | yes | care value framework | no |  |
| Bee 2014 | NR | single with verification | Cochrane RoB tool and Cochrane NRCTs | single with verification | no | - | no | - |
| Tappenden 2012 | single but broader research team agreed on whether the study should be included | NR but very likely single | Cochrane RoB tool | NR, probably single | yes | PICO criteria: interventions delivered at home, relating to a UK context | no | difficult to differentiate between appicability and context/setting... Decided to say no for applicability |
| Brown 2016 | duplicate | duplicate | EPHPP quality assessment tool for quantitative studies | duplicate | yes | methodological tool for the assessment of the implementation of complex public health interventions in systematic reviews | no | data extraction |
| O’Mara-Eves 2013 | NR (5 were involved in searching but not clear if duplicate or single) | duplicate | modified Cochrane RoB tool, EPPI-Centre tool for process evaluation methodology | NR | rather no | - | no |  |
| Bambra 2015 | single with 10% duplicate check | rapid acceleration | integrated in data extraction, no specific tool reported | NA | yes | methodological tool for the assessment of the implementation of complex public health interventions in systematic reviews | yes | no tool: study results were applied to international and UK contexts and implications discussed separately according to these two contexts |

Table 2. Health effectiveness (3)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study ID** | **intervention integrity** | **sustainability** | **heterogeneity** | **tool for clinical heterogeneity** | **statistical tools** | **integration qualitative &quantitative studies** | **subgroups** |
| Balzer 2012 | no | no | yes | narrative result summaries | forest plots | no | no |
| Fröschl 2013 | no | no | no | - | - | no | no |
| Korzcak 2012 | no | no | no | - | - | no | no |
| HIQA 2014 | no | no | yes |  | random-effects meta-analysis assessment of statistical heterogeneity | no | yes |
| Tice 2016 | no | no | yes | no pooling |  |  | no |
| Bee 2014 | yes: intervention acceptability and facilitators and barriers to implementation | no | yes |  | Mas, RE models, I2 | yes | yes |
| Tappenden 2012 | No | no | yes | "heterogeneity was explored through consideration of the study populations, methods and interventions" | I2-statistic, visualisation of analysis results | no | no (although mentioned in protocol..) |
| Brown 2016 | yes | yes | yes |  | Q-statistic test + I2 statistic | no | no |
| O’Mara-Eves 2013 | no | no | yes | combination of studies via outcomes, sensitivity analyses for outcome groups | I2 statistic | partly/no??:consultations with stakeholders were considered when designing the data extraction tools | yes |
| Bambra 2015 | yes | yes | yes | sensitivity analyses | I2 statistic, publication bias through Eggers test | no | yes |

Table 3. Economic aspects (1)

| **Study ID** | **Study ID** | **Type of HTA** | **Scope of SR** | **Included evaluation types** | **Number of databases** |
| --- | --- | --- | --- | --- | --- |
| Balzer 2012 | 33.DIMDI\_1 | Systematic review of economic evaluations | Only systematic review of economic evaluations | "- Cost-minimization analysis - Cost-effectiveness analysis - Cost-utility analysis - Cost-benefit analysis" | Integrated into overall search strategy 29 including 1 economic database |
| Fröschl 2013 | 33.DIMDI\_2 | Systematic review of economic evaluations | Only systematic review of economic evaluations | Cost-effectiveness analysis Cost-utility analysis Cost-benefit analysis Cost Analysis (not further defined) | Integrated into overall search strategy 31 including 1 economic database |
| Korzcak 2012 | 33.DIMDI\_5 | Systematic review of economic evaluations | Only systematic review of economic evaluations | Costs studies Cost-minimization analysis Cost-utility analysis Cost-effectiveness analysis | Integrated into overall search strategy 31 including 1 economic database |
| HIQA 2014 | 55.HIQA\_1 | Systemativ review + primary economic evaluation | Systematic review to inform primary economic evaluation and  systematic review of economic evaluations | Full economic evaluations Cost-effectiveness analysis | Integrated into an overall search strategy:  Embase, Medline + 3 economic databases (EED, HEED, HTA database for economic analyses) |
| Tice 2016 | 63.ICER\_2 | Unsystematic review of literature |  |  |  |
| Bee 2014 | 89.NIHR\_1 | Systematic review of economic evaluations | Systematic review to inform primary economic evaluation and  systematic review of economic evaluations | unclear | Generic search:26 Specific search: 3 |
| Tappenden 2012 | 89.NIHR\_4 | Systematic review of economic evaluations | systematic review of economic evaluations | Cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses, cost-consequences analyses, cost-minimisation studies | 12 (not clear if integrated or separate search; in the screening process were included the study search of all questions of the HTA |
| Brown 2016 | 91.NICE\_1 | systematic review of economic evaluations | systematic review of economic evaluations | not specified | integrated into overall search strategy: 10 |
| O’Mara-Eves 2013 | 91.NICE\_3 | systematic review of economic evaluations | SR of economic evaluations (evidence map) AND SR to inform primary economic evaluation | not specified | Generic search Identifying SRs: 6 Identifying primary research: 2 |
| Bambran 2015 | 91.NICE\_4 | systematic review of economic evaluations | systematic review of economic evaluations | unclear | Integrated into generic search: 11 |

Table 3. Economic aspects (2)

| **Study ID** | **additional efforts in searching** | **single or duplicate searching** | **quality assessment tool** | **generalisability/transferability** | **presentation of cost data** | **method for data synthesis** | **influence final decision?** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 | handsearching, no specific economic sources | duplicate | Drummond et al | no | as reported | narrative | no (reported as separate research question) |
| Fröschl 2013 | - integrated into an overall search strategy (not specified for economic evaluation), - request at the of institutions at the Federal Ministry of Health, Webpage of institutions, reference check | duplicate | not reported (no studies were identified) |  | NA |  | NA (no studies identified) |
| Korzcak 2012 | handsearching (not specified)/no specific economic sources | duplicate | Tool of the German Scientific Working Group Technology Assessment for Health Care | no | as reported | narrative | unclear |
| HIQA 2014 | - | NR | ISPOR questionnaire to assess the relevance and credibility of modelling studies | no | currency conversion into Euro | narrative | yes: terms of reference by the health information and quality authority and the department of health |
| Tice 2016 |  |  |  |  |  |  |  |
| Bee 2014 | - No economic specific additional sources - hand searching in selected journals - search in reference lists of articles - targeted author searches - key researchers were contacted via email with a list of inclusion criteria for the review and a request for information regarding any studies that they felt may be relevant - search for ongoing research via metaRegister of Controlled Trials (mRCT) - forward citation searching via Web of Science - Dissertations Abstracts International database - Websearch for grey literature and material generated by user-led or voluntary sector enquiry - stakeholder consultation | duplicate | Drummond et al | no | unclear | narrative | unclear |
| Tappenden 2012 | Websearch in Google Scholar to identify any relevant unpublished literature hand-searching of included studies | duplicate | Drummond et al | No but only studies from own country included | as reported | narrative | unclear |
| Brown 2016 | (Not specified for economic studies) - Website search (google) - grey literature searches (OpenGrey, Social Care Online, Prevention Information & Evidence eLibrary and Nexus UK) - International Standard Registered Clinical/Social Study Number registry - National Research Register - bibliographies of all included studies were hand searched - experts in the field and authors of ongoing studies were contacted | three reviewers not further specified | Effective Public Health Practice Project Quality Assessment Tool for Quantitative Studies (not specified for study types) | no | as reported | narrative | unclear |
| O’Mara-Eves 2013 | (not specified for economic evaluations) - contact with authors of identified key studies that were excluded on methodological grounds to ask them if they had outputs that would meet our inclusion criteria, or if they could provide further information | unclear | Consensus on Health Economic Criteria (CHEC) | not reported (no studies were identified) | currency conversion, inflated | narrative | NA (no studies identified) |
| Bambran 2015 | - website searches  - grey literature searches - hand search: bibliographies of all included studies, last 2 years of the most common five journals revealed by the electronic searches - requested of information on unpublished and in-progress research from key experts in the field | single with 10% random sample checked by second reviewer | not reported (no studies were identified) | NA | NA | NA | NA |

Table 3. Economic aspects (3)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study ID** | **Primary economic evaluation** | **Evaluation type** | **Comparator** | **perspective of analysis** | **Costs considered** | **valuation of outcomes** | **modelling approach** | **sensitivity analyses** | **presentation of results** |
| Balzer 2012 | no | *-* |  |  |  |  |  |  |  |
| Fröschl 2013 | no | *-* |  |  |  |  |  |  |  |
| Korzcak 2012 | no | *-* |  |  |  |  |  |  |  |
| HIQA 2014 | yes | cost-utility analysis, budget-impact analysis | routine care | societal perspective | direct and indirect (medical and non-medical) | NR | Markov | probabilistic | Narrative, tables and figures (cost-effectiveness-plan, cost-effectiveness acceptability curve) |
| Tice 2016 | no | *-* |  |  |  |  |  |  |  |
| Bee 2014 | no | *-* |  |  |  |  |  |  |  |
| Tappenden 2012 | no | *-* |  |  |  |  |  |  |  |
| Brown 2016 | no | *-* |  |  |  |  |  |  |  |
| O’Mara-Eves 2013 | no | *-* |  |  |  |  |  |  |  |
| Bambran 2015 | no | *-* |  |  |  |  |  |  |  |

Table 4. Sociocultural & legal (1)

| **Study ID** | **specific social aspects addressed** | **theoretical framework** | **Assessment method** | **Explicit implications for HTA** |
| --- | --- | --- | --- | --- |
| Balzer 2012 | social aspects: factors that influence risk of falls, consequences of falls, especially in the elderly ethic aspects: ethic issues for the implementation of interventions to prevent falls i.e. for patients in need of care with cognitive restrictions, use of restrain and seclusion no cultural aspects addressed | not specified | literature review, narrative data synthesis | yes: - Individual preferences and experiences influence should be considered when to decide on preventive measures. - Social support from relatives and friends are important - combination with other advantages in health care would improve acceptance of time requirement - social status influence use of prevention measures - socio economic factors are not important |
| Fröschl 2013 | not specified/no limitation identified aspects:  '- Risk factors for alcohol during pregnancy: member of higher social strata (financially, education), higher age, smoking, other addictions, family history of abuse, experience of being abused, non-migrant population  - (located in the ethics and legal section): social stigma of women drinking alcohol during pregnancy / respectful approach necessary - (located in the ethics and legal section): social role of alcohol in the society, role of partners - Alocohol related care should be continued after delivery | not specified | literature review | yes: - More research is needed regarding interventions that affect alcohol at societal level - Respectful approach to affected women is necessary - More research is needed regarding risk groups |
| Korzcak 2012 | Access to services for cry babies, aspects identified and presented for each study separately | no | literature review (SR, narrative data synthesis) | yes: - Availability of services does not correspond with need for services - Explore the exclusion of low income families/ families with lower educational status from service  - Better education and training for staff, also for staff in services with low-threshold access, including: psycho social factors during pregnancy that promote excessive crying and development of preventive interventions for the risk population (see p. 63) |
| HIQA 2014 | Issues addressed:  • Acceptance of the technology • Consequences of more people that survive resulting in more people with complications and disabilities. • Psychological consequences of people using AED, society’s expectations on the impact of the program and Burden for people working in places were AEDs are available • Implementation in rural or high-density areas (where is it more important) • Promotion of the program • Will of the patient | Eunetha Core model | Mixed methods: The methodology used in this analysis is described in the EUnetHTA core model.(192). A review of studies describing the experience of other countries in the implementation of public access defibrillation programmes was conducted alongside discussion by the evaluation team and the Expert Advisory Group to explore each of the domains included in the assessment. (p. 167) | yes: The placement of AEDs in public locations is generally well accepted in society and has received widespread support from patient groups and professional bodies.   While the intervention is associated with better outcomes for individual out-of-hospital cardiac arrest patients, public access defibrillation may result in an increase in the absolute number of patients surviving with severe neurological impairment who are dependent on others for daily support.   All participants should be made aware of the likely effect of the public access defibrillation programme on survival from out-of-hospital cardiac arrest and the probability of an AED being used in any given location.   Staff in designated places should not feel pressured into participating in the programme if they do not feel comfortable with the prospect of intervening in a medical emergency to perform CPR and or defibrillation.   Alternative ways of improving out-of-hospital cardiac arrest survival should be considered in areas that are not likely to benefit from a national public access defibrillation programme |
| Tice 2016 | not specific question but still somehow adressed in report | Care value framework | Mixed methods:  - Literature review,  - 34 semi-structured telephone interviews with key stakeholders of prevention programs, We sought perspectives from federal and state government, public and private payers, public and private purchasers, patient advocacy organizations, and vendors,  - Consultants conducted semi-structured interviews with national and California-based experts to gain their perspectives on the practice and delivery of DPPs, barriers to change, and opportunities for improving program delivery. These key informants included DPP providers, professional societies, patient advocacy organizations, public health organizations, purchasers, and health plans - policy roundtable discussion | Yes (specify):  Tailor DPPs to include culturally-appropriate curricula for America’s diverse populations: |
| Bee 2014 | 1. mircosocial context: parenting, familiy status, role of partners/fathers, family context, residency arrangement, social network  2. Macrosocial: sociodemographic factors, educational status, SES  3. Cultural: ethnicity  - associations between intervention effect and … child age group, parental mental health condition, family structure and residency - acceptability of community-based interventions … with specific reference to intervention uptake, adherence and patient satisfaction - to assess key factors influencing the acceptability of and barriers to the delivery and implementation of community-based interventions for improving QoL in children and adolescents of parents with SMI  Identified aspects: - child custody losses  - conflicting life circumstances  - social isolation - stigma Preliminary data suggests that children may value peer interactions and normalising activities, although further research is needed to confirm these findings. | Theoretical Framework (HRQoL) = defined by stakeholder consultations (Within the current review, three separate consultation exercises were undertaken) | Mixed methods: ☒Literature review of qualitative and/or quantitative studies: Acceptability was assessed via quantitative and qualitative designs, independently selected those that were eligible and extracted synthesized all relevant data using a textual narrative approach. Studies undertaken in any country were eligible, no restrictions were placed on date of publication. Case studies, opinion papers, descriptive studies, editorials and non-English-language publications were excluded. Qualitative studies eligible for inclusion in our acceptability synthesis were assessed for quality using the Critical Appraisal Skills Programme (CASP) tool for qualitative research and the principles of good practice for conducting social research with children | yes: see DE form for content details |
| Tappenden 2012 | *[No social/cultural/legal evaluation]* |  |  |  |
| Brown 2016 | “To explore if and how socioeconomic status (SES), sex, ethnicity and age moderate the effect of the interventions.” The secondary outcomes of this review were any differential effects of the interventions by sociodemographic status (age, ethnicity, sex) or SES (as measured by education, income, occupation, social class, deprivation or poverty), or interventions that were targeted at disadvantaged groups  Identified aspects: - Age, sex, education, social indicators were measured in studies  - Only few studies analysed these factors as moderators, among those there is none on SES | none ((theoretical framework only with respect to study design and quality: Egan et al) | SR with search strategy on any intervention related to community pharmacies. Design: controlled studies that allow for assessing causation | Yes: - People who attend community pharmacies differ from people who attend other settings - Further research is needed:  No study assessed the differential effects of any measure of SES Future pharmacy-based interventions, and evaluations of them, should be robustly designed, particularly with regard to contextual factors, including the organisation, implementation and delivery of interventions. They should also be sufficiently powered to detect small changes in behavioural outcomes and any associated equity effects.) |
| O’Mara-Eves 2013 | *[No social/cultural/legal evaluation]* |  |  |  |
| Bambra 2015 | *[No social/cultural/legal evaluation]* |  |  |  |

Table 4. Sociocultural & legal (2)

| Study ID | **other important information** | **Legal aspects adressed** | **Assessment method** | **informed consent** | **alternative forms of consent** | **privacy and data protection** |
| --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 |  | yes | hand search for literature | for "Sensormatten" | for "Sensormatten" |  |
| Fröschl 2013 | Underreporting in Germany likely: Often not adequately adressed in the medical history. Misconception by women who consider limited amounts of alcohol as not necessary to be reported + feeling shy to report alcohol use during pregnancy | yes | SR | no | no | no |
| Korzcak 2012 | Relevant information presented in the background (studies from 1991-2001)  Risk factors are: stress, fears in regard to the baby (e.g. preterm) or pregnancy related changes, depression, relationship problems, problems with family, childhood problems of the mother, social isolation, socio economic problems | no |  |  |  |  |
| HIQA 2014 |  | yes | Applying law to the technology (analysis done by a faculty of law) | yes:In the use of AEDs, no consent is usually obtained due to the emergency circumstances that pertain. Therefore the defence of implied consent and the doctrine of necessity would justify and render lawful unconsented resuscitation and other necessary treatment of an unconscious person as such treatment is considered to be in the person’s best interests. (p.179)  for people that does not wish to be resuscitated | yes:In the use of AEDs, no consent is usually obtained due to the emergency circumstances that pertain. Therefore the defence of implied consent and the doctrine of necessity would justify and render lawful unconsented resuscitation and other necessary treatment of an unconscious person as such treatment is considered to be in the person’s best interests. (p.179)  In the absence of case law on this point and given the simplicity of the AED and its reliability, although not obliged to do so, a layperson would probably be justified in using one in an emergency situation when a more qualified person is not available. It is unlikely that a rescuer would be expected to consider the best interests of a collapsed person in anything other than a superficial way governed by the belief that the great majority of victims of sudden cardiac death would wish to be resuscitated. (p.179)  From both an ethical and legal perspective, if the person’s wishes are clearly obvious at the time of the arrest, those wishes should be respected. (p.180) | no |
| Tice 2016 |  | yes but No specific question that addresses leagl aspects | Mixed methods:  - Literature review,  - 34 semi-structured interviews with key stakeholders of prevention programs, We sought perspectives from federal and state government, public and private payers, public and private purchasers, patient advocacy organizations, and vendors,  - Consultants conducted semi-structured interviews with national and California-based experts to gain their perspectives on the practice and delivery of DPPs, barriers to change, and opportunities for improving program delivery. These key informants included DPP providers, professional societies, patient advocacy organizations, public health organizations, purchasers, and health plans - policy roundtable discussion |  |  |  |
| Bee 2014 |  | no |  |  |  |  |
| Tappenden 2012 |  |  |  |  |  |  |
| Brown 2016 |  | no |  |  |  |  |
| O’Mara-Eves 2013 |  |  |  |  |  |  |
| Bambra 2015 |  |  |  |  |  |  |

Table 4. Sociocultural & legal (3)

| **Study ID** | **market authorisation of medical devices/medicinal products** | **clinical trials** | **intellectual properties** | **reimbursement in PH care systems** | **special medical fields** | **explicit implications for HTA** | **other information** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Balzer 2012 |  |  |  |  |  |  | Liability for consequences of falls in nursing homes Appropriateness of restrain and seclusion |
| Fröschl 2013 | No | no | no | no | no |  | Legal custody of the child. Mothers of a child with fetal alcohol syndrome can loose the legal custody of their child because the wellbeing of the child is considered to be in danger. 64% of the mothers of a child with fetal alcohol syndrome have lost the legal custody.These mothers are considered to be at risk who need preventive interventions and treatment. |
| Korzcak 2012 |  |  |  |  |  |  |  |
| HIQA 2014 | No | no | no | no | no |  | Liability: • Persons are not obligated to use AED,  • not liable in negligence for any act in emergency situation, exempt the person owes a duty of care to assist the victim (e.g. physician),  • Duty of care • liability of the owner of the place where a AED is available • obligations for the owner of places with AEDs and liability in case of malfunction ... |
| Tice 2016 |  |  |  | Yes (specify):  - coverage of DPPs by all payers, public and private, is necessary to achieve large-scale impact. (p. 12) - engage in pay-for-performance (P4P) contracts in which are based on the number of people who enroll and achieve certain attendance and weight loss goals, rather than receiving a fee per health plan enrollee or employee offered the DPP. (p. 12) - Description of the different reimbursement mechanism (health plans – private and Medicare/Medicaid, employers, Purchaser Coverage) (p. 16-18) |  | Yes (specify):  - Cover DPPs from CDC-recognized providers across all lines of business and products. Make them available with zero copayments to encourage participation. (p. ES17, p. 56) - Establish pay-for-performance (P4P) contracts with DPP providers based on patient participation, retention in program, and achievement of weight loss goals. (p.ES17, p. 56) |  |
| Bee 2014 |  |  |  |  |  |  |  |
| Tappenden 2012 |  |  |  |  |  |  |  |
| Brown 2016 |  |  |  |  |  |  |  |
| O’Mara-Eves 2013 |  |  |  |  |  |  |  |
| Bambra 2015 |  |  |  |  |  |  |  |

Table 5. Ethical aspects

| **Study ID** | **Normative-ethical research question posed (based on self-identification as ethical question):** | **Normative framework chosen to answer question:** | **Methods employed to answer question:** | **Which ethical issues are identified by the analysis (if relevant):** | **Explicit implications for the HTA:** |
| --- | --- | --- | --- | --- | --- |
| Balzer 2012 | Which potential “ethical problem areas” have to be considered in the implementation of fall prevention programs and which options for action are described? | Normative framework not explained/definition of ethical problem areas not provided. The introduction/inclusion criteria seem, however, to stipulate a certain understanding of ethical issues: balancing benefits and risks, the potential conflict between patient autonomy/non-health related strains and possible health gains in fall prevention measures and how to solve it. | Information is systematically searched and narratively synthesized. Relevant aspects are identified and described in the report. No quality appraisal conducted. Social and ethical aspects are discussed together. | (1) The perspectives of older people on fall prevention measures, especially what factors influence their decision to utilize fall prevention measures (2) How to balance individual autonomy and health protection in the application of fall prevention measures, especially regarding patients with cognitive disorders (e.g. dementia) and high demand of care  (3) Frequency, consequences and motives for using measures involving deprivation of liberty in long-time care facilities | Yes (specify): The discussion refers explicitly to the ethical issues. The concluding recommendations emphasize looking at individual preferences and the importance of reducing the use of measures involving restriction of liberty. This can be seen as influenced by the ethical analysis. |
| Fröschl 2013 | Which ethical, social, legal, and organisational aspects have to be considered [in prevention programs for foetal alcohol spectrum disorders]? | Normative framework not explained/ no definition of "ethical aspects" provided | Information is systematically searched and narratively synthesized. Relevant aspects from the perspective of the author team are identified and described in the report. No quality appraisal conducted. Ethical and legal aspects are described and discussed together. | (1) The negative consequences - e.g. avoiding contact with the healthcare system - of stigmatising alcohol consumption during pregnancy [(2) The risks of negative consequences of losing custody] (3) Societal responsibility for reducing alcohol consumption Issues (1) and (3) are later identified as ethical, issue (2) as legal. | Yes (specify): The discussion refers to the ethical-legal-social aspects. When discussing gaps in research it is pointed out that the effect of a society-wide change of attitudes towards alcohol on pregnant women needs further academic attention. In the concluding recommendations the importance of treating pregnant women with alcohol problems respectfully is emphasized. These points could be seen as a consequence of the preceding ethical discussion. |
| Korzcak 2012 | Ethical, legal and social issues are addressed jointly. The questions addressed under this mixed label are: (1) To what extent is the care (access to care) for children and parents who suffer from excessive crying guaranteed [in Germany]? (2) What must be done to improve care? What enabling conditions need to be put in place? | None, as the questions are not normative in kind | Literature search for relevant studies (in conjunction with search for effectiveness and economic studies). A quality appraisal was conducted. Outcomes of studies were extracted and described, strengths and weaknesses evaluated and evidence level stated. | None | Yes (specify): Based on one of the included studies, strategies for improving the situation for families suffering from excessive crying are made. Two of the studies are not really considered in drawing conclusions from research findings. |
| HIQA 2014 | What are the ethical implications of the public access defibrillation programme? | Principlism | Application of the four principles (respect for autonomy, beneficence, non-maleficence, justice) to identify and discuss ethical issues. Some of the ethical issues identified are then taken up and discussed by the legal analysis, attempting to "solve" these issues. The legal analysis also identifies normative issues. | 1) Would it be acceptable for a non-professional to conduct resuscitation without informed consent in an emergency situation?  (2) Is the risk of harm incurred by having non-trained bystanders conduct resuscitation justified in the light of the potential benefits? How do we manage this risk adequately?  (3) How much responsibility to promote public health can the state legitimately delegate to private actors? | Yes (specify): Ethical-legal issues are touched upon in the summary and conclusion section, but focus is on effectiveness and economic arguments. Executive summary (p. 19): It is reasonable to defibrillate on the basis of implied consent and the doctrine of necessity. |
| Tice 2016 | *[No ethical evaluation]* |  |  |  |  |
| Bee 2014 | *[No ethical evaluation]* |  |  |  |  |
| Tappenden 2012 | *[No ethical evaluation]* |  |  |  |  |
| Brown 2016 | *[No ethical evaluation]* |  |  |  |  |
| O’Mara-Eves 2013 | *[No ethical evaluation]* |  |  |  |  |
| Bambra 2015 | *[No ethical evaluation]* |  |  |  |  |