A Social Prescriptions Formulary: Bringing social prescribing on par with pharmaceutical prescribing

Short title: A Social Prescriptions Formulary

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"Social prescribing is a way of linking patients in primary care with sources of support within the community to help improve their health and well-being[...]Schemes commonly use services provided by the voluntary and community sector and can include an extensive range of practical information and advice, community activity, physical activities, befriending and enabling services."[1]

Social prescriptions have been used in healthcare systems worldwide for several decades because they are thought to promote well-being, prevention and self-care.[1] Social prescribing is being promoted at several levels in the UK from local initiatives at the GP practice level, to regional programmes like Ways to Wellness (a seven year programme in the west of Newcastle that offers social prescribing for up to 3,500 patients at any one time)[2], new social prescribing networks that have been created across the country[3] and national initiatives like NHS England's Universal Personalised Care plan which announced an investment in 1000 Link Workers by 2021.[4]

Despite its promise and widespread use in the UK and internationally, Bickerdike et al. found that "current evidence fails to provide sufficient detail to judge either success or value for money."[1] In their systematic review of 15 studies involving link workers who met with patients to identify their needs and subsequently directed them to appropriate services (e.g. physical activity-based services, welfare and debt advice, counselling, self-help groups, lunch clubs, etc.) within their community, the authors highlighted a high risk of bias in the studies for several reasons including[1]:

- unclear selection criteria of patients

- small sample sizes: usually less than 100 participants with a greater than 20% loss to follow up
- incomplete and heterogeneous outcomes data: though the primary outcome measures in the studies were for health and well-being, there was great heterogeneity in the use of standard clinically validated measures (e.g. Warwick-Edinburgh Mental Well-being Scale, Hospital Anxiety and Depression Scale, General Anxiety Disorder-7, etc.) and bespoke measures[1]
- short follow up periods: from immediately post-intervention up to 4 months post-intervention

This leaves us in a position where we, as a healthcare community, are delivering a set of interventions that may be delivering no benefit and may be causing harm because of side effects or the opportunity cost entailed in diverting finite healthcare resources to potentially low value interventions. As an international healthcare community we must actively establish the evidence base around social prescriptions to understand what role they can play.

In this manuscript we outline how formularies, supported with non-randomised control trial mechanisms to capture evidence, could be used to rationalise the use of social prescriptions and ensure they deliver better patient and population outcomes while optimising resource utilisation.

Formularies

Pliny, in the first century AD, is credited with creating one of the first pharmacopoeia, a guide for pharmacists on how to create remedies for various health ailments.[5] Pharmacopoeia evolved into formularies which collect, filter, fillet and provide prescribers essential information on drugs to ensure safe and effective prescribing.[6] One of the most long standing and well established formularies is the British National Formulary (BNF) which has been used by UK and non-UK healthcare professionals since 1939 to guide prescribing decisions.[6] In recent years, formularies have been used locally and nationally as a mechanism to promote rational prescribing and cost containment (Box 1) in the face of rising healthcare costs and a proliferation of drugs available for prescribing.[6, 7] These experiences suggest that the development of a Social Prescriptions Formulary, and perhaps a Social Prescriptions Pharmocopoeia, could help to promote the standardisation of social prescription-based interventions and the rational prescribing of social prescriptions to ensure their use is effective, efficient and high value.

Box 1: Benefits of Formularies

Formularies promote rational prescribing through well-established mechanisms[8]:

- Weighing of comparative efficacy
- Decreasing bias/conflict in decision-making
- Cumulative expertise reviewing drugs
- Accounting for pitfalls and biases
- Identification of potential for misuse
- Weighing benefits vs. risks and costs
- Prioritisation of resource allocation
- Highlighting safety concerns
- Guidance and warnings education
- Monitoring/oversight of institutional use

Evidence suggests that formulary use at local, regional and national levels increase utilisation rates of formulary drugs and reduce costs, yielding prescribing practices that are appropriate, safe, cost-effective and, ultimately, value-based.[9, 10,11]

Building a Social Prescriptions Formulary

Creating and using a social prescriptions formulary requires several steps: evidence generation, evidence synthesis, establishing pricing/reimbursement and building formularies (Fig 1).

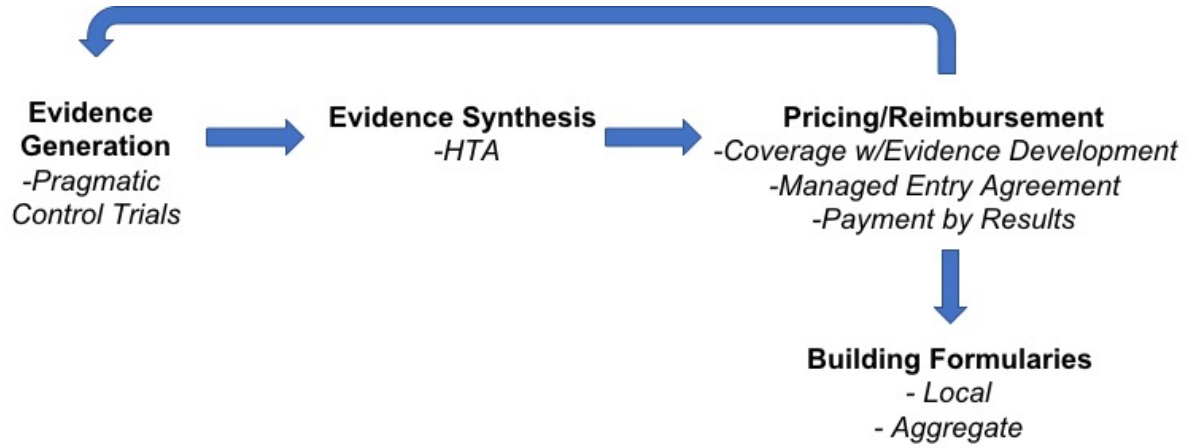

Figure 1: Creating and using a Social Prescriptions Formulary

Evidence generation

Key limitations of the current evidence on social prescriptions include poor study design, small sample size and exposure to bias.[1] Overcoming these barriers will require better studies but, unlike the case for pharmaceuticals that deal with chemical compounds, blinded randomised control trials, though the gold standard, may not be necessary for social prescriptions. Given the ability to rapidly modify social prescriptions, alternative methods of evidence generation like pragmatic control trials, which measure effectiveness as opposed to explanatory trials which measure efficacy,[13] and implementation frameworks, which aim to identify methods that can promote the implementation of research findings into practice,[14] may be more practical means of generating the evidence base around social prescriptions. Further to this, certain pricing mechanisms (see below) may also contribute to the generation of evidence on social prescriptions.

There is also precedence for using alternate approaches to creating formularies, a good example being the UK Children's BNF where available evidence was supported by clinical

experience of paediatricians and paediatric pharmacists because of a lack of clinical trial data for use of drugs in children.[6]

Evidence synthesis

Health Technology Assessment (HTA), the standard for evidence synthesis, is defined by the WHO as "the systematic evaluation of properties, effects and/or impacts of health technologies and interventions" that can be "used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies".[15] Because of its independence and strong reliance on rigorous, transparent scientific methods, HTA is an essential resource to support decision making on how to account for the cost-benefit of social prescriptions.

Pricing/Reimbursement

Universal healthcare systems use several mechanisms to control market access and pricing for pharmaceuticals. Given the nascent nature of the evidence around social prescriptions, some of these mechanisms (direct price controls such as external reference pricing and value-based pricing; and indirect price controls such as internal reference pricing and utilisation of economic evaluation) may not be immediately applicable but may be utilised in the future when the evidence base for social prescriptions is more robust. In the interim, however, pricing mechanisms within the scope of utilisation control (not including envelope agreements, price volume agreements or capping) may be more relevant, particularly:

- Coverage with Evidence Development: interventions are reimbursed but confirmation is contingent on the collection of additional population-level evidence

- Managed Entry Agreements: interventions are reimbursed subject to specific conditions (e.g. evidence of impact)
- Payment by Result: interventions are reimbursed only if certain results are delivered[12]

Another key consideration around pricing and reimbursement is proper coding which can facilitate consistent and systematic collection and sharing of data. This can be done at local levels but ideally should be set nationally using systems like SNOMED CT so comparisons can be made across different geographies, within and between countries, to garner context-dependent and -independent models that deliver value and which can guide decision making.

Building formularies

Though we may not be able to immediately create national Social Prescriptions formulary, local and regional formularies could be developed to aid in the use and evidence generation on the use of social prescriptions, all of which could be used to create a more robust national formulary. Indeed, there is a substantial evidence base around the creation and implementation of GP-level and regional formularies that rationalise prescribing, an approach we are planning with the Royal College of GPs (RCGP) Research Surveillance Centre, a sentinel network of 400 GP practices across England.[6, 10,11]

Using these general approaches combined with a more recent set of recommendations from FLIP (Formulary Leveraged Improved Prescribing), could see clinicians actively engaged

in deciding which social prescriptions to include/exclude from their formularies based on a standard set of questions adapted from the FLIP project[8]:

1. Evidence of need: Is there compelling evidence of a need to add this social prescription to our formulary?
2. Efficacy: What is the strength and quality of evidence to support claims for this social prescription?
3. Safety: What safety issues need to be considered?
4. Misuse impact potential: If placed on the formulary, what is the potential for misuse or overuse?
5. Cost Issues: Can we justify the cost of this social prescription?
6. Decision-making information, calculations, timing and process: What is the quality and completeness of evidence and deliberations of the formulary committee?

An additional consideration is that advanced IT capabilities (artificial intelligence, machine learning, Internet of Things (IoT)) combined with new formulary creation software, such as FormularlyComplete,[6] could facilitate the creation and implementation of formularies with data aggregated across multiple GP practices, regions and nations. Indeed, the RCGP is in the pilot stages of a project to explore how IoT could be used to support these processes.[16]

Furthermore, utilising wearable sensors could enable the continuous collection of dynamic types of data required for analyses to elucidate microtemporal processes relevant to health-promoting behaviors.[17] If this data is linked to personal health profiles that inform case-mix-calculations and outcome measurements, prescribers can receive tailored prescribing

recommendations, researchers can access data and patients can access predictive models that can help them compare themselves against their reference population and receive credible feedback on the health benefits incurred as a consequence of their adherence to different social prescriptions.

Social prescriptions delivering value

Though the evidence for social prescriptions is limited, the potential for them to deliver higher value healthcare by promoting well-being, prevention and self-care shows great promise.

Given the evidence-base behind formularies being able to drive rational prescribing, a strong case can be made that to tackle the lack of robust evidence on the outcomes and value for money delivered by social prescribing highlighted by Bickerdike et. al,[1] a Social Prescriptions Formulary (local, national and international) can deliver clear benefits for all healthcare stakeholders:

- Patients: increased choice and information about the risks and benefits of evidence-based social prescriptions
- Prescribers: decreased risk associated with using social prescriptions because of greater standardisation and evidence-base behind social prescriptions
- Payers: ability to negotiate and bulk purchase standardised social prescriptions and greater transparency on the value of purchases

- Providers of social prescriptions: standardisation and bulk purchases from payers would allow for more stable and predictable revenue streams (which could also facilitate economies of scale, competition and innovation)
- Policy makers: data on regional and national use of social prescriptions would facilitate more rational resource allocation decisions

It is important to note that though formularies have obvious strengths, there are drawbacks as well including the fact that they can limit clinical autonomy, sometimes focus too much on cost containment and can create bureaucratic hurdles for clinicians and patients.[8] In addition to this, for social prescriptions specifically, there is a risk that formularies could over-medicalise interventions that are aimed at addressing social factors and there is also a risk that standardization could prevent people benefiting from local innovative initiatives that are not included in formularies.

Despite the potential limitations, though, there is a hope that successfully built and utilised social prescriptions formularies could lead to the eventual harmonization of social prescriptions, as we have seen with pharmaceutical prescriptions, through entities like the European Medicines Agency, and, in the UK, the incorporation of social prescriptions in a more comprehensive BNF that includes all interventions aimed at improving health more generally.

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