Uncovering a new approach to developing clinical based guidelines: The experience of developing guidelines for management of drug dependent women and neonates; and for cannabis dependence.

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Abstract

Rationale, aims and objectives: In the management of health care problems there are circumstances where there is only weak or indirect evidence on which to base clinical decisions and advice. As clinical guidelines assume an increasing role in funding and regulation of health care, and in medico-legal issues around practice, the strength of evidence becomes increasingly important. *Method*: This paper describes and reflects on the experience of a systematic process of synthesizing research findings with expert consensus to develop guidelines using an extension of the methods developed by Kettil Bruun. The process involves the use of trigger papers that systematically review the available evidence; discussant papers that critique evidence-gaps and develop draft guideline statements; and a workshop of practitioners and researchers who synthesize and debate the areas of clinical practice. Two separate projects conducted in Sydney, Australia are used to illustrate the process. *Results and Conclusion*: In this process, high levels of consensus were reached even in contentious areas. However, the process is time-consuming and requires considerable commitment from experts.

Keywords: Evidence Based Practice, Guidelines, Expert Consensus, Kettil Bruun

1. Introduction

There are many clinical areas that elicits highly emotive responses from sections of society, and is consequently politically sensitive far beyond what the fiscal or social costs would suggest. Social responses are heightened when the user is seen to be vulnerable or culpable in certain ways – for example youth or pregnant women. At the same time, treatment modalities for drug dependence for example are frequently enmeshed in professional controversies, while research that could add light is constrained by thorny and sometimes unresolvable ethical concerns. This paper seeks to describe a process by which safe guidance for clinical treatment within current social and political constraints can be developed in the absence of clear research evidence, using instead a consensus process based on the shared expertise of clinicians.

From the mid 1950s to the 1980s, Kettil Bruun, a Finnish alcohol researcher with a commitment to collegial work in a community of scholars, became known for his innovative fostering of robust debate among his peers. He developed a reputation for 'asking the unthinkable and organizing ways to answer it', and then, further putting that knowledge 'to work in the world' [1]. He drew together various groups of professionals with diverse views and facilitated and focussed discussion until consensus was reached on pivotal decision points [2]. This unique scholarly method has been systematised in this paper into an approach to developing clinical guidelines which provide a comprehensive, coherent and consistent approach to various aspects of clinical care even where evidence is limited. The process involves 7 steps (see figure 1) and is specific to areas where there is confusion, no consensus, poor practice or lack of research. The first and central step is to develop a clear definition of the problem area. This embraces Bruun's [2] approach to consider the unthinkable, ie uncertainly about treatment a specific client group. Following problem definition is the establishment of a steering committee, which determines the target audience and scope of the guidelines. The steering group then commissions experts to review the available published evidence on identified topics, and synthesize the evidence in a "trigger paper". This is then critically reviewed by another expert in the field, and gaps in the evidence are identified, leading to a "discussant paper". The trigger and discussant papers are then circulated to a group of people with recognized and respected expertise in the field. Practitioners subsequently meet in a workshop setting with the aims of reviewing the strengths,

limitations and gaps in evidence, and as a result establishing best practice in the form of a guidelines document. The agreed decisions are then formalised into statements in a published document.

The process itself is not new. One of the seminal publications guiding practitioners delivering methadone maintenance was the 1983 NIDA Research Monograph Research on the Treatment of Narcotic Addiction [3]. This comprised review papers, discussant papers, and workshop proceedings discussing the clinical implications. However, what is different about more recent publications is the focus on systematizing professional practice, and use of the concept of "guidelines" - something not mentioned in the NIDA Monograph, which is described as a "reference".

The trend towards increasingly prescriptive systematisation of health care is accelerating. Since ancient times, there have been recommendations about appropriate care of the sick [4], but in the last half century such recommendations have become increasingly systematized into clinical guidelines, policies and procedures. In the complex, resource-intensive systems of contemporary health care, such protocols are recognized as essential to maintain safety, effectiveness and accountability. Policies and procedures are definitive protocols. Where less certainty can be garnered, 'guidelines' are developed which preference adherence but do not mandate it. Clinicians may use their judgement and expertise, while those who depart from the guidelines are advised to carefully document their rationales. An indication of the role of guidelines is that at October 2011, the US National Guidelines Clearing House website lists 2343 electronically available guidelines and 280 guidelines in progress.

The recent intensity in the rise of guidelines has been associated with the development of evidence-based medicine (sometimes generalised to 'evidence based practice' or EBP). EBP involves the use of scientific methods to systematically establish a hierarchy of evidence about the value of a given intervention in health care, minimizing practitioner bias and, through meta analyses, providing objective summaries of data or 'evidence' on which to base clinical decision making. With an increasing volume of published research evidence, the focus has turned from practice guidelines to guidelines that are systematic, evidence-based and include information on

processes, structures, and incentives that support the effective use and evaluation of such guidelines [5]. For clinical experts in the field, the challenge is to create clinical guidance that is safe, reliable and consistent while the evidentiary basis is scant or absent.

Despite their popularity, guidelines are not without limitations. Guidelines must be applied in a specific context to a specific client. This may not be as straightforward as the text in the guidelines would suggest, and depends on factors which include the specific setting (eg rural vs metropolitan), the experience of the clinician and the complexity of the client. A significant limitation of guidelines relates to the limitations of the evidence on which they are based. Dartnell and colleagues [6] suggest correctly interpreting results of studies is a central hurdle for developing appropriate and reliable guidelines. In the hierarchy of evidence the randomized control trial (RCT) is often considered the "gold standard" of research design. Evidence based medicine itself has historically lionised the place of the RCT at the head of the hierarchy of evidence, however there is ongoing debate within professional circles about the limitations of the RCT and what constitutes the most credible 'evidence' in a given field or context. Not all clinical questions can be answered by an RCT design and in many cases applying this design to population health settings is likely to encounter methodological, pragmatic, and theoretical limitations [7]. In addition, ethical considerations constrain the design of high quality studies, such as the optimal double blind randomised controlled design, which would be difficult or impossible to implement with a population of pregnant women and drug exposed infants. Pilling and Price [8] detail four limitations of RCTs for developing guidelines, including the limited nature of the patient population, limited follow-up and narrow outcomes, efficacy of interventions and their comparators and the competency of therapists. These challenges led Sackett [9] to suggest that "good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough." (p, 72). In this light, the processes described herein aimed to address the growing dissatisfaction with the methodology of addiction research as highlighted by Orford [10]. He suggested that not only has treatment been asking the "wrong question in the wrong way" (p1) but there is a need to marry lay knowledge from the public (or patient centred outcomes) and experts.

Perhaps most importantly of all, the extent to which guidelines alter practice is questionable, and this constitutes a major limitation. For example, after the problem of deaths during induction onto methadone was identified in Australia in the early 1990s, training programs for doctors were introduced, with an emphasis on safe induction, and new and more cautious guidelines for induction were promulgated in most jurisdictions. Despite these measures, over the next five years there were further deaths, often the result of prescribed methadone doses greater than recommended in guidelines, and it was concluded that training and guidelines appeared to be frequently ignored [11]. This pessimism may have been premature. A study in the UK reported that, while initially guidelines had little impact on prescribing practices, over time the influence of guidelines became more apparent [12].

Because of the need for expert opinion in areas where evidence is lacking, the "Kettil Bruun" style of developing consensus has been employed recently in Australia to develop guidelines. The current paper briefly describes the background and process involved in the development of two guidelines in Australia using this process (although there are others in recent years which have also relied on this method [13]) and reflects on the strengths, weaknesses, and lessons learned.

2. Method

Guideline 1: Guidelines for the Management of Pregnant, Drug-Dependent Women and their newborn infants [14].

The impetus for the development of these guidelines came from increasing concerns and increasing public awareness over the deaths of young children of drug-dependent women. During the 1990s, reports on child deaths identified that children of drug dependent parents were heavily over-represented among child fatalities [15]. A controversial recommendation of the Child Death Review Team (CDRT) was that newborn children of drug-dependent women should be kept in hospital until all symptoms of Neonatal Abstinence Syndrome (NAS), and the need for treatment of NAS, had ceased. This recommendation did not match current clinical practice, causing concern among clinicians treating NAS on an outpatient basis with little evidence to support either practice. NAS results from the woman's opioid use during pregnancy, including

the prescribed opiate substitute methadone hydrochloride. The prescribing of drugs for pregnant women, more particularly drugs which may produce NAS, and most particularly prescribing to pregnant women suspected of being poor citizens and worse parents, remains a highly emotive issue. The development of guidelines with broad multidisciplinary support, grounded in the best available evidence, is therefore crucial. To address issues of stigma related to drug use during pregnancy, it important to link obstetricians and neonatologists with drug and alcohol specialists so that the women are not marginalized, and seen as marginal by mainstream medicine (as 'methadone clinic-dwellers'). This consensus building process aims to reduce the sense of ownership over clients so instead they are owned by all the stakeholder groups.

At this time there was widespread concern in the community about the issue of drug use and child protection, and several expert committees (National Expert Advisory Committees on Alcohol (NEACA), tobacco (NEACT) and illicit drug (NEACID)) had recommended development of guidelines for management of illicit drugs, tobacco and alcohol in pregnancy. There was also a move to explore early intervention strategies to enhance the parenting capacity of drug-dependent parents. Government funding was acquired and all Australian governments – State, Territory and Federal – shared the cost of the project under the National Drug Strategy, through the Ministerial Council on Drugs (MCDS). This involvement of all levels of government was essential for the acceptance and promotion of the final product in this highly controversial area.

The objective in developing these guidelines was to comprehensively review evidence about the impact of drug use during pregnancy; to identify research gaps; and to ascertain the degree of consensus on recommendations for management. The target audience was determined by the funding agreement, which required that the guidelines be written in a way that would be accessible to all those clinicians who may work with substance dependent pregnant women or their infants, whatever their level of training. The final document therefore would have to be couched in user-friendly language and an accessible style. The first step was to form a steering committee of 24 members, which consisted of relevant expert drug and alcohol clinicians and representatives of other relevant stakeholders including the national Aboriginal Community Controlled Health Organisation (NACCHO], the Australian College of Midwives, the Drug and

Alcohol Nurses Association (DANA), the Royal College of Nursing Australia, the National Drug and Alcohol Research Centre (NDARC), the Royal Australian College of General Practitioners, the Perinatal Society of Australia and New Zealand, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and representatives from each government jurisdiction: state, territory and federal (and included author JB as chair). A project officer [JM] was employed to conduct the project under the direction of the steering committee, and the work of identifying topics and reviewers was undertaken. Specific concerns relating to patterns of substance use in Aboriginal and Torres Strait Islander communities were identified, and a working group of 11 including the project officer [JM] was established to review this evidence [14].

Step 2, identification of topics by the steering committee, resulted in the selection of sixteen topics for review of evidence and the writing of trigger and discussant papers, including the separate but parallel review of issues in Aboriginal and Torres Strait Islander communities. The sixteen topics included both specific substances and a range of other issues of significance. Specific substances identified for review were alcohol, tobacco, opioids including both heroin and prescribed substitution therapies, cannabis, benzodiazepines, amphetamine-type substances, cocaine, and inhalants. Other crucial topics identified were: a review of current Australian protocols for the management of substance-dependent women and of neonates exposed to drugs in utero, based on protocols supplied by hospitals around Australia; evidence for the best management of neonatal abstinence syndrome; psychosocial issues for substance-dependent pregnant women and parents of neonates; breastfeeding and toxicology; vertical transmission of blood-borne viruses; obstetric implications; pain management in labour, delivery and the immediate postnatal period; and implications for the early childhood years.

Steps 3 and 4, commissioning of key experts to write trigger and discussant papers, held a particular challenge in that no funding was available to pay these reviewers. This is a fundamental challenge to the outlined process. In this case example, it was agreed that writers would retain copyright of their own work at the end of the process, and may undertake to publish their review independently at a later date. Sometimes with considerable negotiations but with widespread good will, arrangements were reached with the necessary experts to produce 30

[trigger and discussant] papers on the 15 non Aboriginal topics. The reviews of evidence relating to Aboriginal and Torres Strait Islander community issues was undertaken in an additional workshop, and these trigger and discussant papers were ultimately combined into one paper, making the total of 16 topics. In inviting experts to participate, people from all around Australia were identified because of concerns that in some hospitals or some cities, local practices might become entrenched. Leading figures were invited to write trigger papers on the key issues, and discussants, usually from different States to the trigger paper authors, were asked to provide comment, and have a first attempt at drafting guidelines in the areas covered by their discussant paper. As anticipated, experts identified that on many important issues, there was limited or low-grade evidence, hence the importance of attempting to draft guidelines reflecting best practice prior to the workshop.

Initially, there was some difficulty in achieving engagement of the experts in the processes of writing and participating in discussions. Some clinicians remained disengaged, feeling they would rather publish a review article than undertake a review to put towards a workshop. Some undertook to do the reviews and failed to deliver. However, despite these difficulties, the project team was able to put together a set of expert trigger and discussant papers that formed the background to the workshop [14]. The critical factor in putting it together was the persistence of the Project Officer [JM] employed to ensure that papers were completed and distributed on time. Once the project was underway, the initial diffidence of some participants disappeared, and many others became eager participants in an increasingly exciting process.

Once all trigger and discussant papers were completed and circulated to [and read by] all participants, step 5 was undertaken in the form of a two day workshop. The aim of the workshop was to achieve consensus on each key clinical decision point using the trigger and discussant papers as reference material. A secondary aim was to ensure all disciplines engaged in the care of pregnant drug dependent women and neonates were represented in order to ensure that the guidelines reflected multi-disciplinary care practices and would have broad endorsement in the sector. Workshop delegates included the authors of both the trigger and discussant papers as well as leading clinicians and researchers in the field. There were forty participants from medical, nursing and allied health backgrounds with the support of a number of jurisdictional authorities.

In addition, a prominent American clinician-researcher was invited and asked to present an overview of the literature as a trigger paper. This was one of the measures designed to avoid risks of parochialism.

The final composition of the workshop participants resulted in a high level of interaction and discussion, carefully brought back to the topic by the facilitator [AR] while allowing exploration of issues and producing integration of addiction medicine, paediatrics and obstetrics. The facilitator is required to focus discussion and debate until consensus statements are agreed, or points of disagreement crystallised. In this case, the discussion achieved a high level of consensus, perhaps partly because workshop participants were acutely aware of the significance of this workshop which brought together for the first time drug and alcohol specialists, obstetricians, midwives, paediatricians and nurses, and the realisation that where consensus could not be reached by participants face to face, it was unlikely to be reached subsequently. Issues of disagreement were discussed and unravelled in depth until some level of agreement could be attained which did not omit any crucial point. No consumers were included in this workshop, although it is acknowledged that inclusion of consumers in future projects would both allow consumers a voice, and enhance the outcomes.

To aid the final step, the development of the guidelines post workshop, and to avoid potential misinterpretation or later variations in recall of the agreements, the workshop was audio recorded and subsequently listened to by the project officer [JM]. Capturing the discussion in this way allowed the subtlety of controversial points of disagreement to be translated into words that accurately reflected the best possible interpretation in the final guidelines document. It also allowed for a checking process in the event of a challenge from workshop participants to the accuracy of the guideline statements developed. The actual development of the guidelines document was led by the project officer [JM] through a process of organising those consensus statements agreed at the workshop into coherent sections, and augmenting those with the development of careful statements based on the discussion where consensus could not be reached. For each topic, the statements were sent for review first to the authors, then to all workshop participants. Comments were reviewed and incorporated through consultation until agreement was again reached. The statements were collated into a single document, organised

according to the topics, and was circulated first to key clinicians around Australia identified by representatives on the steering committee. After incorporation of those comments, the subsequent version of the document was referred to the funding body, the Ministerial Council on Drugs, for approval. After the publication of the guidelines document in 2006, the background papers (combined trigger and discussant papers) were also published in order to ensure the source evidence was available to all clinicians [16].

Guideline 2. Guidelines for the management of cannabis related issues [17].

Research into cannabis related problems has dispelled the once popular belief that cannabis is a benign drug with little harm associated with its use. While there is not enough information for a meta-analysis, significant gains have been made in the range of effective interventions for dependent cannabis users. However, there is concern that these developments are not being translated into practice. The guidelines were designed to provide clinicians with a synthesis of the research into the screening, assessment, and management of cannabis related problems and to equip clinicians with tools and knowledge to deliver evidenced based interventions.

The guidelines development process followed the Kettil Bruun approach as documented here. Key experts [n=11] were invited to write or co-write trigger papers [n=7] that summarised the evidence and n=9 experts were invited to write discussants papers [n=7] that reflected on that evidence and provided first stage guideline recommendations. The authors were identified from their academic and clinical experience with cannabis. Not all papers were of a peer-review standard and not all discussant papers prepared guideline statements as requested. The same problems as occurred in the previous case example occurred here. The importance of clarity in instructions to authors of the trigger and discussant papers was reinforced. In addition, there may need to be incentives for authors (such as subsequent peer-review publication of the trigger paper), especially given the amount of time devoted to a systematic review of the evidence. The majority of authors worked in academic settings which may have supported reports being completed in a timely fashion. Regular communication between the project officer [AF] and authors, well documented timelines and clear details of the commitment of each author also aided this process.

Workshop participants [n=21] included 10 available authors of trigger and discussant papers and 11 field clinicians selected on their experience delivering cannabis interventions. No consumers were included. As with the previous example, the workshop was audio-recorded. There was a high degree of consensus among the workshop participants and its facilitator [AR]. This is perhaps not surprising given that the many of the major researchers in the cannabis field were at the workshop and this format is less likely to result in direct disputation of their peers contribution to the field. That said, clear and clinically viable suggestions for treatment were offered in the absence of grade A, or sometimes any evidence. In addition, this workshop was much smaller in number [n=21 versus n=40 for pregnancy], leading to greater ease of consensus within the workshop.

The iterative process involving the guidelines project manager [AF] and the authors / workshop participants continued for twelve months following the workshop. Difficulties were noted in engaging workshop participants to comment on drafts after the workshop, with some workshop participants more engaged in the process than others. A final draft was then circulated amongst six independent clinicians with varying degrees of experience with cannabis for detailed comments on the readability and useability of the guidelines.

3. Discussion

Rycroft-Malone [18] noted that incorporating clinical consensus with clinical evidence must be done in a way that is systematic and rigorous, and eliminates as much bias as possible from the process. However, as Shekelle and colleagues [19] observe, there is no optimum way of marrying these two processes. At one end of the spectrum, where evidence is clear and disagreement is limited, the author of the discussant paper may be able to draft guideline statements that could be refined in the workshop. At the other end of the spectrum, where decisions are most controversial, evidence is scant and sometimes contentious. and decisions most controversial, In these situations, the conduct of the workshop is vital to reaching expert consensus. Consistent with our experience, research indicates that a facilitative chairperson is one of the most important ingredients for successful outcomes [20, 21]. A disadvantage can be the difficulty in obtaining trigger and discussant papers that meet the needs of the process, as

detailed in both case examples. In addition, in these cases, consumers were not included in either workshop – an area to be rectified in future processes.

The process can be very time consuming. In the two practical examples described it is a highly collaborative recursive process in which papers may require multiple revisions and further input after the workshop, and thus an ongoing commitment from the authors and workshop participants is required for the life of the project. Close management of interactions following the workshop is vital. All revisions and communications with individual authors should be channelled through a coordinator or lead editor. This ensures that direct disagreements between participants are avoided, distracting issues such as interpersonal rivalry are minimised, and control of the final outcome (and style) by the steering group is optimised. A question about the efficiency of the process could nevertheless be asked. While no cost benefit analysis of such processes has been conducted, the authors consider that the time and effort invested are commensurate with the outcomes and contribution to improved client care, that is, well worth the effort. Since it is a process used to compensate for significant gaps in the research, the time and effort invested should at least reflect the not inconsiderable time and effort required by a research project. In this consensus process, differing points of view and experiences must be thoroughly explored to develop the desired consensus. Additionally, due to the high level of interaction needed, it is recommended that the workshop participants be limited to 20 however there is only limited research available to guide the optimum number of key informants, and effective workshops have been held with greater numbers.

The strengths of this process are numerous. The use of evidence in combination with clinical consensus is a useful guide to clinical practice when evidence is sparse. Multiple reviews of the evidence involving a wide panel of experts with clinical experience safeguards against poor clinical practice. Recommendations in the guidelines are explicitly linked to the evidence base. The use of an interdisciplinary collective approach enhances the credibility of the guidelines and may lead to a better uptake of guidelines in clinical practice across a wide range of disciplines. A summary of key tips is outlined in Table 1. There are also limitations inherent in this guidelines development process. It is labour intensive, and requires willingness of experts to prepare systematic reviews of the evidence; experts to review and provide discussant papers and

sufficient time available for all to participate in a workshop. Incentives are required, as most experts are enormously busy people. It also requires effective project management skills and clear and concise communications about the scope of the final product from the outset. The workshop is a demanding process with participants debating and making decisions on many areas. This requires the skill of an experienced facilitator to manage the group processes and dissension.

Despite these limitations, we have demonstrated through two case examples the successful establishment of clinical guidelines in two important areas of alcohol and drug practice. The process, relying heavily on multiple inputs from key experts within a structured framework, has the potential to produce practical and quality guidelines. The next question is whether and how guidelines can improve practice and the quality of care our clients/patients receive and associated clinical outcomes.

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Figure 1: Flow chart of process

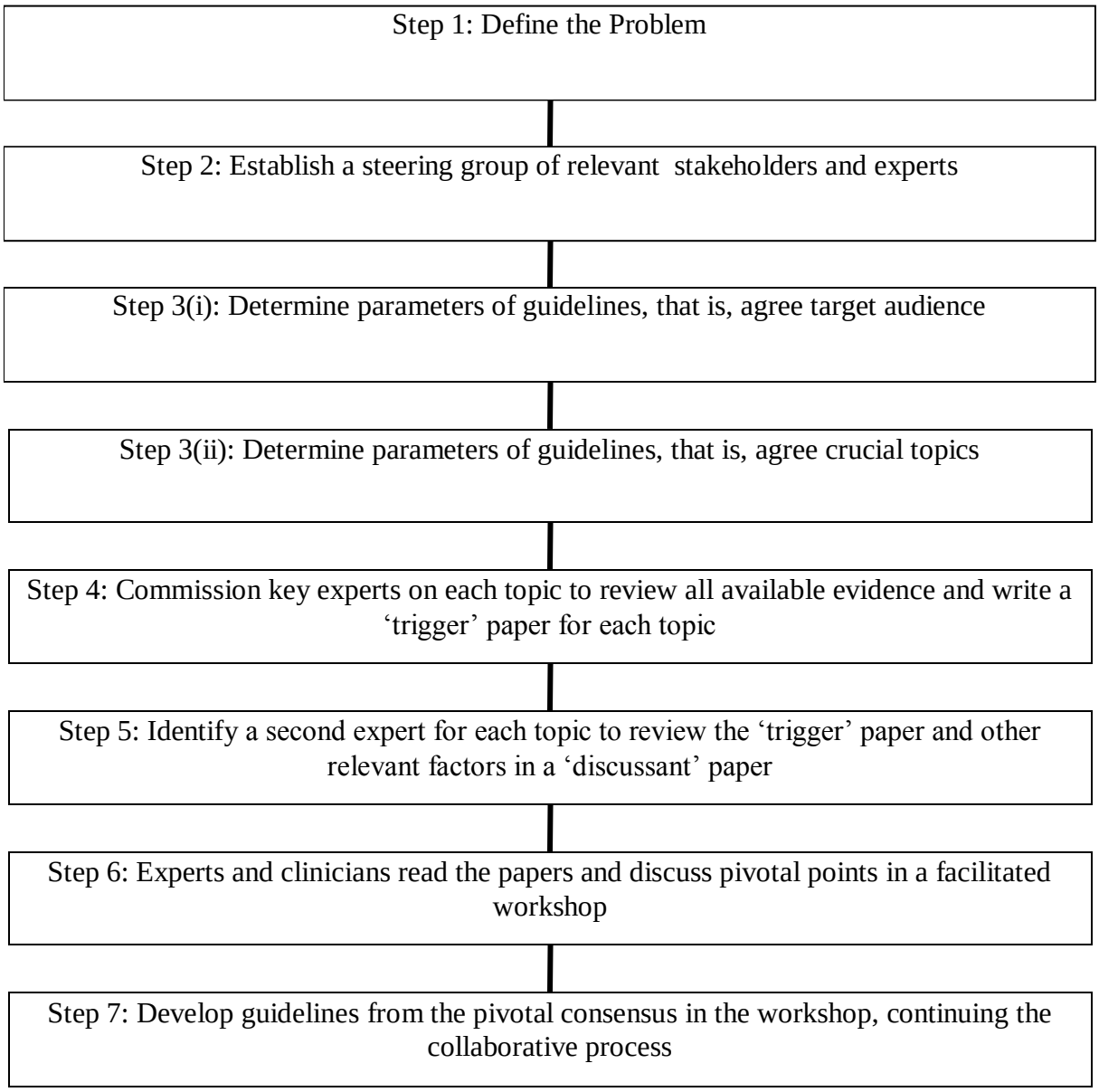

Table 1:

Key tips for following an expert consensus guidelines development process

Process	• Focussed leadership including scope of intended final guidelines product and its target clinical audience(s). • Inviting feedback from clinicians in the field improves credibility and hence the uptake of the final guidelines. • Identifying a designated person to coordinate the process ensures continuity. • Clear communication around expectations and timelines for all involved is important from the start. • Provide authors with examples of guidelines that have appropriate content / format. • Multi-disciplinary considerations. • Incentives for people to be involved (given workload, time commitment).
Trigger papers	• Authors need clear guidance on how to review studies. • Clear parameters for the scope of the review should be set with each author [this includes discussions of grey literature, no-human studies, word length for example]. • Appropriate timelines should be negotiated. • Suggested format for authors: Introduction / Evidence / Recommendations / Summary.
Discussant	• Suggested format for authors: • Identification of crucial issues • Guidelines emerging and level of evidence to support guidelines • Recommendations or "good practice points' identified (where insufficient evidence for making a guidelines, and consensus make be expected) • Areas lacking consensus • 5) Gaps in available evidence, and recommendations for further clinical research.
Workshop	• An experienced facilitator is key to the success of the workshop. • Audio recording of the workshop keeps an accurate account of the discussion and decisions made for reference. • Inviting a diverse yet small number of workshop delegates promotes robust debate.
Draft and final guidelines	• Ongoing involvement of authors of trigger and discussant papers post workshop. • Iterative process. • Clear lead authorship of final product. • Product endorsement by relevant professional bodies.