extracted relevant data about the reported clinical trials. For this assessment, a coding book was operationalized and specifically tailored to the context and role of IBs. The coding book included items on the reporting of a) a search strategy to find relevant evidence b) a method of evaluating the risk of bias of included studies and c) a data collection and syntheses procedure. The coding book included a second set of items to evaluate the reporting quality of all clinical trials listed in the IB.

Results A total number of 321 clinical trials were identified in the 30 IBs. Despite the relatively similar aims of evidence reporting in IBs and systematic reviews, no IB reported a search strategy that could have demonstrated how comprehensive the reported clinical evidence is. Furthermore, no IB presented a risk of bias assessment for the reported studies. All of the included IBs reported the results of relevant clinical trials exclusively in a narrative form and did not use any method to synthesize the evidence to create a concise overview of the results. The majority of the 321 trials reported the sample size (96%, $n = 308$), blinding (83%, $n = 266$), and randomization (66%, $n = 212$). Specific details, however, about sample size calculation, randomization methods or blinding procedures were reported for less than 1% of the 321 studies reported in the IBs. Baseline characteristics and participant flow were reported for 10% ($n = 31$) of all 321 trials.

Conclusions IBs serve the important function to compile the evidence that shall justify the approval and conduct of a planned clinical trial. Our results in a random subsample of 30 IBs that reported on 321 clinical trials show that IBs do not adhere to any established principles of evidence synthesis known from systematic reviews. In sum, our findings cast doubts about the robustness and transparency of decision-making based on the evidence provided by IBs. In particular, it raises the question whether they enable the above-mentioned reviewers to conduct a meaningful risk-benefit assessment that is ethically and legally required to justify clinical trials. In the presentation, we will outline recommendations on how to improve evidence reporting in IBs.

43 GENERATING GUIDELINE RECOMMENDATIONS – EXPLORING PATIENT VALUES?

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Objectives The National Cancer Control Programme (NCCP) began developing national evidence based clinical guidelines in 2012. In 2017 we decided to generate our guideline recommendations using the GRADE process. There is clear guidance on appraising the quality of the evidence and performing bias assessments. However, the challenge begins with the integration of the best evidence, benefit and harm, patient values and resources when generating recommendations. Patients are full members of the guideline development groups; however, the question remains how do we truly capture patient values? By inviting a philosopher/medical ethicist to be a member of the GDG, integrating patient values has been explored in our update of the national clinical guideline diagnosis staging and treatment of patients with prostate cancer.

Methods A guideline development group was established with representatives from diagnostics, surgery, oncology, nursing,

research, patient representatives and a philosopher/medical ethicist. The guideline questions were generated by the GDG. Literature searches, appraisal of the evidence and data extraction were performed by the NCCP research team. Generation of recommendations by the GDG follows a formal standardised protocol using an evidence to decision framework developed in NCCP. The following items are considered; the evidence, its quality its generalisability/directness, benefit and harm, patient values, resources and cost. The evidence statements are written in real time and recommendations graded strong or weak. During the first meeting to generate the guideline recommendations the philosopher challenged the group to consider the meaning behind words such as. generalisability, equity and justice. We also explored patient important values such as pain, certainty, anxiety, quality of life, trust, choice and autonomy.

Results Our evidence to decision framework has been restructured to contain a matrix to explore patient values for each option under discussion. New headings have been added with prompts to stimulate discussion with emphasis on patient important outcomes, equity, acceptability and a richer exploration on the concept of generalisation. Each evidence statement now has clear headings for quality of the evidence, benefit and harm, patient values and resources. Framing the discussion in this manner resulted in a richer conversation. For the first clinical question under review there was high level evidence, however the clinical members in the group were concerned that recommending a course of action could lead to greater inequity within our health system. This has resulted in escalation of the GDG recommendations within the health service with service redevelopment proposed.

Conclusions Involvement of the philosopher/medical ethicist led to the development of clear questions, prompts and a matrix, in the patient values domain. This resulted in the GDG having greater confidence in exploring patient values when generating guideline recommendations. This would challenge guideline developers to expand the membership of their GDG to include this expertise. Of most importance this led to a richer discussion and resulted in more consideration being given to a recommendation even in the presence of high-level evidence. As a result, there is earlier engagement with the services to enable implementation of the recommendations with fidelity to ensure we do not create further inequity within the health services.

44 OPENING THE BLACK BOX OF 'USUAL CARE' AND FINDING A BLACK HOLE: A NUMERICAL SYSTEMATIC REVIEW ON 'USUAL CARE' CONTROL GROUPS IN STROKE REHABILITATION RCTS

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Objectives Ethically, in every experimental trial new methods should be tested against the 'best' or, if not defined, the 'usual' care according to current Guidelines. To understand the latter, we focused on stroke rehabilitation as a case in point because stroke is a leading cause of disability and rehabilitation is a complex intervention whose need is increasing due to growth of chronicity and disability (World Health Organization). Our aim was to appraise stroke rehabilitation