Title: Addressing unwarranted clinical variation: A rapid review of current evidence

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Abstract

Introduction: Unwarranted clinical variation (UCV) can be described as variation that can only be explained by differences in health system performance. There is a lack of clarity regarding how to define and identify UCV and, once identified, to determine whether it is sufficiently problematic to warrant action. As such, the implementation of systemic approaches to reducing UCV is challenging. A review of approaches to understand, identify and address UCV was undertaken to determine how conceptual and theoretical frameworks currently attempt to define UCV, the approaches used to identify UCV and the evidence of their effectiveness.

Design: Rapid evidence assessment (REA) methodology was used.

Data sources: A range of text words, synonyms and subject headings were developed for the major concepts of unwarranted clinical variation, standards (and deviation from these standards) and healthcare environment. Two electronic databases (Medline and Pubmed) were searched from January 2006 to April 2017, in addition to hand searching of relevant journals, reference lists and grey literature.

Data synthesis: Results were merged using reference-management software (Endnote) and duplicates removed. Inclusion criteria were independently applied to

potentially relevant articles by three reviewers. Findings were presented in a narrative synthesis to highlight key concepts addressed in the published literature.

Results: A total of 48 relevant publications were included in the review; 21 articles were identified as eligible from the database search, four from hand searching published work and 23 from the grey literature. The search process highlighted the voluminous literature reporting clinical variation internationally; yet, there is a dearth of evidence regarding systematic approaches to identifying or addressing UCV.

Conclusion: Wennberg's classification framework is commonly cited in relation to classifying variation but no single approach is agreed upon to systematically explore and address UCV. The instances of UCV that warrant investigation and action are largely determined at a systems level currently, and stakeholder engagement in this process is limited. Lack of consensus on an evidence-based definition for UCV remains a substantial barrier to progress in this field.

Background

Clinical variation (UCV) is identified across health systems.[18] Determining clinical variation that is problematic and/or preventable is a continuing challenge, with a lack of consensus regarding how this can be defined and routinely identified.[8, 63] The Agency for Clinical Innovation (ACI) in New South Wales, Australia define unwarranted clinical variation (UCV) as ‘variation that cannot be explained by the condition or the preference of the patient; it is variation that can only be explained by differences in health system performance’ e.g. the effectiveness of the structures, processes and services that form any given health system.[6] This form of variation may pose a significant challenge to achieving equitable healthcare and to enabling all patients to receive evidence-based treatment.[7] If UCV exists, it is possible that healthcare professionals and services are not consistently adhering to evidence-based

guidelines. Identifying services and practices where variation is common is therefore critical.

Reducing UCV is identified as a priority of several health systems internationally.[11-13] In New South Wales, Australia, the ACI have established a taskforce focusing on reducing UCV but determined that confusion amongst health service providers and consumers regarding how best to identify and interpret UCV is a barrier to progress.[1] For example, country-level data present rates of variation, but there is a lack of clarity regarding how these rates should be interpreted.[14] Without UCV guidelines for policy makers, managers and clinicians that are easy to access and apply, systematic approaches to reducing UCV cannot be implemented. To assist policy-makers to start to address this issue, a rapid review was commissioned by the ACI to address the following questions:

1. How do conceptual or theoretical frameworks currently attempt to define UCV?
2. What approaches or strategies have been used to i) identify/determine variation as UCV and/or ii) address UCV?
3. What evidence is there of the effectiveness of the approaches identified in addressing UCV?

METHODS

This literature review utilised a rapid evidence assessment (REA) methodology. This research methodology uses the same methods and principles as a systematic review but makes concessions to the breadth or depth of the process to address key issues about the topic under investigation.[15, 64, 65] An REA provides a balanced assessment of what is already known about a problem or issue, and the strength of evidence. The lower cost, relative to full systematic reviews, make REAs helpful for informing healthcare decision makers.[16] In the present review, REA was used in order to provide a focused review to address policy questions. The search was therefore limited to contemporary literature (post 2006) identified from two major electronic databases and grey literature that explicitly used the term ‘unwarranted clinical variation’. A rapid review of UCV amongst paediatric populations was published in 2016; we sought to complement and build on this existing review by studying only adult studies.[66] The REA was structured using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses—PRISMA statement.[17]

Eligibility criteria

Inclusion criteria

- *Types of publication:* Publications in the English language that reported original primary empirical or theoretical work published from 2006-2017.

- *Types of settings:* Public or private hospitals, day procedure centres, general practice or other primary/community care facilities that included an adult population (18 years plus).
- *Types of study design:* Conceptual, theoretical, quantitative or qualitative studies of any research design.
- *Outcomes:*
 - Conceptual or theoretical frameworks used to identify and/or understand warranted or unwarranted clinical variation in relation to any healthcare outcome AND/OR
 - data regarding the identification and/or assessment of unwarranted clinical variation in relation to any healthcare outcome.
 - Given the plethora of studies on clinical care variation and the lack of consensus in definition, only studies explicitly using the term ‘unwarranted clinical variation’ were eligible for inclusion.

Exclusion criteria

Non-empirical literature such as opinion pieces, letters and editorials and studies that employed hypothetical vignettes were excluded.

Study identification

Electronic databases

A range of text words, synonyms and subject headings were developed for the three review questions of *unwarranted clinical variation, standards (and deviation from these)* and *healthcare environment*. These text words, synonyms and subject headings were used in searching two electronic databases that index journals of particular relevance to the review topic (Medline and PubMed) from January 2006 to April 2017. Two slightly different strategies were employed to address research question one (see supplementary file 1) and research questions two and three (see supplementary file 2). Hand searching of reference lists of published papers ensured that relevant published material was captured. Results were merged using reference-management software (Endnote, version X8) and duplicates removed.

Grey material

Qualitative studies reported in the grey literature (e.g. reports and papers published by government departments, intragovernmental agencies, public or private health service providers, non-government agencies, consumer organisations, professional bodies, advocacy groups) were identified by searching the websites of relevant organisations (see supplementary file 3 for a list of the relevant organisations included). Literature identified was assessed along with the papers from the database searches.

Study selection and data extraction

Three reviewers (SM, RAH, RH) independently screened the titles and abstracts (or executive summaries for grey literature). Copies of the full articles were obtained for those that were potentially relevant. Inclusion criteria were independently applied to the full text articles by each of the reviewer team (all authors). Disagreements were resolved through final discussion between two members of the review team (RH, EM). The following data were extracted from eligible literature: author(s), publication year, sample, setting, objective, framework used and main findings.

Data synthesis

Findings were analysed using a narrative empirical synthesis in stages, based on the review questions.[19] A quantitative analytic approach was not appropriate due to the heterogeneity of study designs, contexts, and types of literature included. Initial descriptions of the eligible studies and results were tabulated (Tables 1 and 2). Patterns in the data were explored to identify consistent findings. Interrogation of the findings explored relationships between study characteristics and their findings; the findings of different studies; and the influence of different outcome measures, methods and settings on the resulting data.

RESULTS

Results of the search

After removing duplications, 2093 records were identified. Title and abstract screening review resulted in 249 references that fulfilled the inclusion criteria, for which full text of the publications were obtained. A total of 49 publications were included in the review based on the inclusion and exclusion criteria; 21 articles were identified as eligible from database full text review; 24 studies were identified from the grey literature and four further studies were identified via hand-searching. Figure 1 shows the selection process.

<INSERT FIGURE 1 HERE>

Excluded studies

Studies were largely excluded from the database search due to lack of explicit UCV focus (n=2074). Many of these studies sought to identify and present different types of clinical variation in specific populations, conditions or practices but presented this with no discussion of what was considered 'unwarranted', undesirable or inappropriate variation. These three terms were used interchangeably in the literature. These studies did not therefore address the review questions. Further exclusions (19)

were due to publication type, e.g. editorial pieces that did not present conceptual or theoretical frameworks.

Review findings

1. How do conceptual or theoretical frameworks currently attempt to define UCV?

Five studies described six frameworks that are used for understanding clinical care variation.[8, 21-24] The uncertainty hypothesis and Wennberg's classification system is presented as a framework for understanding clinical care variation, setting out the effective-care, preference sensitive care and supply-sensitive care categories.[24] A further study uses the uncertainty hypothesis proposed by Wennberg and Gittelsohn, along with Wennberg's classification system for categorising clinical care variation, to form the basis of the Atlas of Variations in Medical Practice in Spain.[9, 21, 25] Bernal-Delgado and colleagues modified the original Wennberg classification system that was developed in a US context, for relevance in Europe and specifically in Spain. The framework presented in the Atlas sets out two components; a value-attribute and a variation attribute. The value attribute assesses utilisation rates of a particular practice to determine whether utilisation is at an 'acceptable' level based on average utilisation rates. A determination is made as to whether any given practice is being undertaken at a statistically significant rate outside of the defined parameters.[21] The variation-attribute indicates whether differences observed across environments can be considered 'unwarranted' based on statistical analysis. The Atlas draws upon the

uncertainty hypothesis to set the statistical parameters and therefore determines whether variation in practice is unwarranted.[21]

A third theoretical paper reports the use of complexity theory – clinical variation emerging from the complex interplay of factors and small components – to explain variations in clinical practice in primary care settings.[23] Variation in the local clinical environment and in the broader geo-political environment adds further complexity.[23] Unwarranted variation in this context is understood by applying complex adaptive system analytical techniques to various quantitative and qualitative data.

Three models are presented in the fourth and fifth paper: the Goodman Model, the Bojkoski Model and the model of Sepucha et al, along with reference to Wennberg's classification system.[8] The Goodman Model focuses on paediatric care and therefore the original paper was excluded from this review of UCV in adult populations.[26] As Mercuri and colleagues indicate that the model may apply beyond paediatric care; it is described here. The Goodman Model suggests that UCV is associated with differences in medical resources, utilisation and outcomes that are associated with differences in health system performance.[8] In this model, UCV is explained by the quality, appropriateness and efficiency of healthcare. Operationalisation of these concepts is not clearly defined.[8]

The Bojakowski Model is a position piece proposing that the degree to which variation is ‘unwarranted’ or ‘acceptable’ is a matter of judgement and cannot be explained by patient needs, local conditions or the broader healthcare environment.[8,20] An absolute measure of whether variation is warranted or not is hard to establish because of complexity in healthcare delivery, population health needs and the multitude of factors that combine to create variation.[20] Rather than defining parameters that highlight UCV during evaluation, , Bojakowski suggests that combining various sources of information and contextualising data is critical to establishing the extent to which variation is unwarranted.[22]

The grey literature search yielded nine documents that discussed conceptual or theoretical frameworks for understanding UCV.[5,27-34] Four of these discussed atlases of variation in Spain, Australia and the UK National Health Service.[27-29, 32] The first of the studies reports on the Atlas of Medical Practice Variation in Spain.[28] In the second, a presentation of the NHS Atlas of Variation depicts the guiding principles of clinical community leadership, widespread engagement, co-production with communities, consistent presentation and messaging and extended reach to NHS decision-makers.[29] Findings indicate substantial regional variations are impacted by the introduction of multi-disciplinary teams but variations are not explicitly identified as unwarranted; the authors note the challenge in defining problematic variation.[29]

The final two studies explore how to identify UCV based on the Australian Atlas of Healthcare Variation.[27,32] The main overview of the Atlas presents details from three national health datasets: the Medicare Benefits schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and the Admitted Patient Care National Minimum Dataset (APC NMDS) to explore 36 medical conditions, interventions and procedures as potential areas of UCV.[27] More than 100 clinicians, epidemiologists and pharmaceutical experts commented on these data. Unwarranted variation is considered by the Australian Commission on Safety and Quality in Health Care to be where variation is ‘not in keeping with what’s best for that person’s healthcare need or their preference.’ [27]

Whilst the Atlas identified very high rates of certain procedures and treatments, such as antibiotic use, colonoscopy and knee arthroscopy, the broad definition of unwarranted variation does not specify how these rates result in categorisation as unwarranted or the possible reasons for this variation.[27] A follow-up report then highlights the need to consider health literacy and shared decision making to understand UCV in the Atlas, given its emphasis on patient preferences and decisions in explaining UCV. The report also highlights a major limitation of the Atlas in its lack of outcome measures collected from Australia as routine data or patient-reported outcome measures (PROMS), limiting understanding of the benefits and harms experienced from healthcare interventions.[32]

Five further documents retrieved from the grey literature discuss three further frameworks: The Wennberg framework (3), Goodman Model (1) and the European Collaboration for Health Optimisation.[30-32,34,35] The Wennberg and Goodman frameworks are described above. The European Collaboration for Health Optimisation was a European Union (EU) funded initiative between 2010-2014 that sought to identify approaches to address UCV in the EU.[34] The project combined patient-level data from Austria, Denmark, England, Portugal, Slovenia and Spain to compare and map UCV within and between countries by exploring the number of observed hospital admissions versus the number expected for the given population.[34] The approach focused on 'effective care' procedures only in order to identify UCV, it is unclear how the approach could be utilised to identify UCV in areas where the evidence is less clear regarding the optimum treatment. The report highlights the value of international benchmarking for identifying variation in particular procedures and for providing a larger pool for statistical comparisons, but is less informative regarding circumstances in which evidence is less clear regarding optimum treatment.[34]

2. What approaches or strategies have been used to i) identify/determine variation as unwarranted and/or ii) address unwarranted variation?

Two groups of studies reported approaches to determine UCV, with suggestions to address UCV. The first group of four studies applied a framework to determine UCV

in population or hospital level data.[21,35-37] The second group of 14 studies applied statistical models, most commonly regression analyses, to identify variation that was considered to be deviating at a statistically significant level from standard, appropriate or expected levels of variability.[38-51]

i. Framework-based UCV identification

The database search yielded retrospective populations or hospital cohort studies (2), along with qualitative interviews (1) and mixed-methods approaches (2) to identify UCV.

The Atlas of Medical Practice Variation in Spain explored population data sets related to three types of practices: 1) effective care, where practices were proven effective for any patient, 2) effective care with uncertain marginal benefit from a risk-benefit analysis in patients for whom there is insufficient evidence of effectiveness and 3) lower-value care, where there is no evidence of effectiveness.[19] The effective care group explored hospital admissions for acute myocardial infarction (AMI), breast cancer surgery, hip fracture repair and colectomy in colorectal cancer. The uncertain marginal benefit group included cases of percutaneous coronary intervention (PCI) in AMI, knee-replacement, carotid endarterectomy and caesarean section births. The low value care group included spinal fusion, prostatectomy and tonsillectomy in children 15 and older.[19] Findings indicate many likely cases of inappropriate care in the

uncertain marginal benefit group for treatments such as knee-replacement and PCI, but that the proportion of inappropriate care varies depending on the number of cases in a given area so patient-level data must be scrutinised. Substantial unexplained variation in endarterectomy were noted, with authors suggesting extensive distance to specialised services and variation in adoption of carotid stenting.[21] High systematic variation was noted in low-value care, with some exceptions. The authors indicate the two likely drivers of variation to be different styles of practice and different adoption of more cost-effective alternatives.[21]

A mixed-methods study using surveys and interviews across case study sites explored the degree to which UCV was a concern, and perceptions of the factors leading to such variations.[35] Survey data indicated that UCV was a concern for 90% of the survey respondents who worked in hospital management at a range of levels or quality and safety departments (n=220), with impact on hospital readmissions as the largest concern.[35] Many of the respondents (75%) reported using strategies in their hospitals to address UCV described below.

The final study utilised the Theoretical Domains Framework (TDF), widely used in determining health behaviours, to qualitatively identify factors perceived to influence practice. The TDF was used to explore factors thought to influence deviation from evidence-based recommendations via interviews based on 12 theoretical domains rather than being used as a framework to understand UCV.[37] Findings suggest that

deviation from evidence-based guidelines in the assessment of patients with mild traumatic brain injury was largely driven by beliefs about the impact on patient outcomes of using assessment or clinical-decision tools, lack of skills and knowledge in the use of the tools and lack of social norms in the specialty around the use of such tools.[37] Environmental pressures relating to high patient throughput was also influential in decision-making about adherence to evidence-based practice guidelines.[37]

The CareTrack study of appropriateness of healthcare delivery in Australia highlighted inappropriate care in terms of adherence with evidence-based or consensus-based guidelines.[36] This definition is often used to identify variation considered as unwarranted. Indicators for 22 common conditions were agreed through consensus with 522 experts. The consensus agreed indicators were used as a framework to determine the proportion of appropriate care identified in medical records and patient interviews. On average it was deemed that appropriate care was provided in only 57% of encounters during the study period, ranging from 13% in alcohol dependency to 90% in coronary artery disease.[36] Whilst the findings demonstrate variable care, they do not necessarily identify UCV; Scott and Del Mar highlight that reliance on consensus-based guidelines means that those areas where there is no single optimum approach may have been identified as inappropriate.[52]

The grey literature search identified eight documents discussing the identification of UCV with reference to frameworks.[5,30,53-58] A presentation on the use of national data tools for commissioning NHS services highlights a range of tools that present indicators of care utilisation and outcomes to guide NHS expenditure in primary care, including the NHS Atlas of Variation.[57] The presentation discusses approaches to understanding variation using these tools but lacks specific guidance regarding the identification of variation that is unwarranted. The NHS Right Care Atlases provide a compendium on three issues: under-use and overuse of treatment, preference sensitive care and better treatment.[54] Whilst the document provides a comprehensive presentation of a range of conditions, the causes of the variations are unclear. A final example is the OECD report regarding geographic variations across 13 countries, with an emphasis on identifying UCV. Substantial variation in high-cost, high-volume activities like cardiac procedures and caesarean section rates are noted across and within countries, yet exploration of the reasons for these variations is limited.[5]

ii. Statistically-defined UCV identification

The second group of studies applied a variety of statistical models for the systematic identification of variation, and the identification of putative factors that either directly identify or indicate potential unwarranted clinical variation. Studies employed retrospective cohort analyses using hospital or population data (11), retrospective chart review (2) and meta-analysis of cohort studies (1). Three studies only employed simple descriptive statistics, data stratification and simple comparative tests (such as

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chi-squared test), or simply presented distributions.[39,40,45] In nine studies, multiple regression models were employed to adjust for covariates and to explore potentially significant interactions between factors.[38,41,42,46-51] These approaches utilise standard multiple regression techniques, parametrised and categorised according to evidence based guidelines, accepted definitions of appropriate care, or by expert panel agreement. Findings often demonstrated significant variations, such as regional variations in time to diagnosis and treatment, but could not definitively report these as UCV.[38]

Two studies utilised or proposed novel statistical techniques.[43,44] Karnon presented risk-adjusted cost-effectiveness (RAC-E); an extrapolation regression model similar to that used in economic modelling. This model utilises multivariate case matching followed by application of extrapolation models to each cohort to predict future costs of healthcare to a horizon point (years), thereby allowing comparison of various clinical processes and their predicted cost efficiencies.[44] Ibanez-Berioz introduced Shared Component Modelling (SCM) coupled with Small Area Variation Analysis (SAVA) and Besag-York-Mollie (BYM) modelling as a method of more accurately distinguishing systematic variation in healthcare, potentially due to UCV.[43] SCM coupled with SAVA and BYM was shown to offer advantages over multiple regression models and studies utilising SAVA (that is geographic variation studies) alone. One further study did not make statistical comparisons and simply reported

observations of deviations from evidence-based guidelines in the treatment of schizophrenia based on 30 quality indicators agreed by an expert panel.[59]

iii. Addressing UCV

Studies largely focused on identifying and defining UCV rather than addressing it. However, approaches for addressing UCV were identified in four articles, often in relation to specific conditions.[24,35,60,61] These studies did not necessarily attempt to provide evidence that approaches were effective. Menon and colleagues explored colorectal cancer against Wennberg's framework, exploring instances of effective, preference-sensitive and supply-sensitive care.[24] The authors highlight the variations in effective care and suggest that investigation of the colorectal cancer care pathway may help to distinguish the points at which unwarranted variations are generated to enable focused interventions.[24] For those variations related to patient-preference, Menon and colleagues suggest that UCV often arises when patients are unable to make informed decisions regarding 'preferences.' Reduced UCV for these types of treatments may be achieved by clinical consultations that focus on relevant treatment options, set realistic expectations and clearly define patients' outcome goals.[24] A number of precursors to UCV are also identified including lack of multi-disciplinary team (MDT) review, suboptimal clinical data, complex disease, variable attendance by MDT team and insufficient time in MDT review.[24]

A second study explored an intervention to challenge UCV in the treatment of chronic non-cancer pain.[60] The intervention aims to address UCV indirectly through patient education regarding explanatory models for pain and the range of treatment options available.[60] Whilst not explicitly identified by the authors, the intervention focuses on variation that is preference-sensitive. The study tracked YouTube views and dissemination of the videos but not impacts on practice.

In a third study, Gauld and colleagues reported a range of strategies identified through interviews with hospital leaders and quality managers to address UCV in acute hospitals.[35] Strategies cited were the use of benchmarking, clinical practice guidelines, blinded report cards, opinion leader education, pay for performance, unblinded report cards and patient engagement.[35] An example of one such strategy was the withholding of performance bonuses for physicians who exceed targets for referred services. The final study is described below (pg. 20) as the focus was on determining the effectiveness of strategies to address UCV in surgery.[61]

Three further articles discussed addressing UCV in the grey literature.[5,13,62] An OECD press release suggests that UCV should be tackled by governments via public reporting and target setting, policies targeting providers and patient-centred approaches using tools for shared decision-making.[5] The National Healthcare Quality Report provided an overview of progress in reducing variations between 2000-2005 in the USA. The report demonstrated that variability reduced for 28

measures, increased for 13 and showed no change for 18 measures. Some of those measures with the greatest variation, such as hospital admission with uncontrolled diabetes, showed no change or increased variation since 2000.[62] The report does not discuss specific approaches used during the time period to address UCV or make links to particular strategies and the figure presented.

The most substantial progress in attempting to address UCV was identified in the Getting it Right First Time (GIRFT) initiative within the NHS.[13] GIRFT is a national review programme led by frontline clinicians in each disciplinary area. It was piloted in orthopaedic surgery and has progressed to 30 medical specialities. The review process utilises a range of data including outcomes and costs of care in a process of peer review. The initial review of the program by the Kings Fund concludes that whilst the programme has substantial potential to reduce UCV and associated costs, this is subject not only to clinician engagement but also managerial engagement and action which may be greater in some Trusts and hospitals than others.[13]

3. What evidence is there of the effectiveness of approaches to date that have attempted to address UCV?

Whilst some studies identified strategies to address UCV, only one study explored the perceived effectiveness of these via surveys of hospital managers.[35] Of the seven

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strategies identified to address UCV described above in section iii, the use of benchmarking and clinical practice guidelines were the most common (used by 66% of respondents) and perceived to be 'somewhat effective' by 72% of respondents. Yet the strategy of patient engagement perceived to be 'very effective' by the most respondents (41%) was the least utilized; only used in 18% of cases.[35]

One further study was identified via hand-searching that provided a literature review of the effectiveness of strategies to reduce UCV in surgery.[61] The authors highlight the challenge of defining UCV, resulting in a focus on those interventions that had an impact on the rates of surgery in any given context. Forty-one studies were included - grouped into two categories of interventions to reduce UCV.

The first category was interventions aimed at the decision-pathway, including the development of new evidence of optimum care, the update and dissemination of evidence amongst clinicians, shared decision-making and the effect of evidence on the provision of surgery for certain disorders.[61] This group of studies demonstrated that evidence of optimum care is essential to identify UCV, but even when such evidence exists, acceptance of new evidence can be slow. Interventions to disseminate best evidence and improve adherence were scarce and demonstrated only very small improvements.[61] Shared decision-making has been consistently identified as the key to reducing UCV in preference-sensitive care categories, with the included studies demonstrating shared decision-making interventions reduced surgery rates for

certain conditions such as knee-replacement and prostatectomy in benign cases.[61]

Despite shared decision-making, there was no direct evidence demonstrating a resulting reduction in UCV.[61]

The second category of interventions included those aimed at healthcare organisations. Interventions included financial and non-financial incentives and direct regulatory and planning approaches.[61] The use and impact of financial incentives was dependent on the health system structure, with differences noted between fully nationalised and free market systems. The latter, largely being influenced by insurers; healthcare utilisation was substantially higher in systems in which individuals mostly obtain at least basic health insurance.[61] Again, the link to UCV is indirect. Non-financial incentives were also identified, with potential for powerful but also unintended undesirable effects. Strategies such as providing increased logistical support were found to be effective in encouraging staff to relocate to areas of need, but not to directly impact UCV. Potential unintended consequences on patient selection were noted as specialists may be reluctant to take on older or less healthy patients.[61] Regulatory approaches include regulation of the number of specialists available in a given area. One such approach is restricting the number of places on a training programme but this was not associated with reduced activity as it takes some years to filter through to practice.[61]

Discussion

The review identified 49 publications presenting conceptual, theoretical or original research regarding the identification of UCV and/or approaches to address the challenge. The search process highlighted a plethora of work exploring types and frequencies of clinical variation internationally; several hundred such studies were identified. Notably, within the evidence base regarding clinical variation, there was a lack of distinction between variation that is warranted or unwarranted, with an implicit suggestion that all variation is problematic. The present review explored what is known to date regarding approaches to identify and/or address UCV from articles that specifically used the term ‘unwarranted clinical variation.’ We explore the implications of these findings for policy makers seeking to reduce UCV.

Whilst a heterogeneous group of articles were identified, the body of evidence demonstrates three key findings in relation to current work around UCV. Firstly, there is a growing body of sophisticated data regarding the clinical variation arising in various health systems internationally and increasingly rigorous data collection approaches evidenced in the atlases of clinical variation.[12, 21] Secondly, a range of statistical approaches can be applied to this data to determine care that is considered to be outside of any given parameters. Finally, when synthesised, this collection of studies highlight the challenge of determining the parameters for UCV beyond the

category of treatments or procedures that are considered to be ‘effective care’; that is, those agreed to be the optimum care for all patients.

The dominant classification systems relating to variation converge on the notion that optimum care in relation to many treatments and procedures is likely to vary dependent on a range of patient and contextual factors.[9,28] In many cases there may not be a single optimal approach from which deviation can be identified and labelled as unwarranted. As such, it is difficult to develop a systematic approach to the operationalisation of frameworks used for categorising types of variation (such as Wennberg’s) in order to identify and address instances in which UCV may be deemed problematic. Work undertaken to date does not provide any conclusive detail regarding how to ascertain what is and is not unwarranted.

The body of evidence demonstrates a substantial and continuing gap in the field of research. Without an understanding of the parameters that distinguish ‘warranted’ and ‘unwarranted’ variation, or the knowledge of if these can in fact be delineated for some procedures or care processes, progress cannot be made to take action in reducing problematic care variation using the approaches identified. Related to the challenge of defining the variation that is unwarranted, is the limited evidence regarding what can and should be done to address UCV, and whether any proposed approaches are in fact, effective. Without clear operationalisation of frameworks to

categorise UCV, assessing the impact of interventions or initiatives to address UCV is also challenging.[8]

In attempting to address UCV in New South Wales, the ACI consider UCV as ‘variation that cannot be explained by the condition or the preference of the patient; it is variation that can only be explained by differences in health system performance.’[1] The definition reflects that of the Goodman Model in conceptualising UCV in the context of health systems performance.[26] Yet this definition is also grounded in the notion of a best practice or optimal approach for every patient and condition, and as such aligns with aspects of the Wennberg model, particularly in relation to the effective care category. The principle of deviation from optimal or ‘effective’ care underpins most of the conceptual frameworks identified here; they are predominantly distinguished by the way in which deviation is conceptualised. It appears that existing models converge on this principle in the absence of data to support an alternative standpoint; Bojakowski is the only model to present a substantially different perspective.[22]

Implications

The review findings have multiple implications for policy and practice regarding UCV. To date, work has focused on identifying variation and classifying this as potentially unwarranted and currently perpetuates the perception that any clinical variation is problematic. There are multiple competing factors that lead to variation

and these are also apparent in cases that appear to be UCV. Simply identifying possible UCV is insufficient to reduce problematic variation. The identification of potential cases of UCV should be a trigger to explore an aspect of the system or a care pathway, rather than being immediately assumed to be problematic.

In the context of the evidence outlined it is unsurprising that few studies have developed and evaluated strategies to address UCV and, as such, demonstrated their effectiveness. One approach may be to establish agreed parameters for determining the point at which variation should be investigated for each condition/procedure or treatment within a health system in order to account for a wider range of potentially appropriate care options for many conditions. A decision tool may then support healthcare services to explore aspects of care in which likely UCV has been detected, to direct action where needed.

Limitations

Limiting the electronic search to two databases, studies post 2006 and the explicit use of the term UCV may have shaped the review findings. A wider scope was beyond the scope of the review, which used REA methodology to undertake a focused review to address policy questions in the Australian context. The omission of studies exploring clinical variation generally without a UCV focus may have also led to the omission of some relevant work, but the evidence-base regarding clinical variation is

vast and not suitable for collation in a single review. Whilst our review offers a starting point, our findings indicate that further comprehensive analysis of the issue via primary research is needed in order to attempt to establish an internationally agreed definition to form the basis of an in-depth systematic review.

Conclusion

Studies included in the review provided no strong evidence of the value of attempts to identify UCV, nor the effectiveness of such attempts. Evaluations of approaches to address UCV were also largely absent. On this basis, the only conclusive statements that can be drawn from the evidence is that there is variation in healthcare provision, some of which may be problematic. Many assumptions are made, particularly in statistical work in which those cases that fall outside of statistical parameters for acceptability are deemed UCV, with no further assessment of the detail of the case.

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Figure 1 Legend

Figure 1: Flow diagram of the selection process

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Table 1: Summary of included journal articles (n=25)

First author	Year	Country	Primary objective	Sample	Methods	Framework	Search
Bernal-Delgado, E	2014	Spain	To explain the Spanish experience of applying an Atlas of variation adapted from the Dartmouth study.	Admissions to the Spanish National Health Service between 2008-2009 (approximately 4 million admissions)	Retrospective analysis of population-level data.	Atlas VPM Conceptual Framework	Database
Bojakowski	2010	UK	To Examine the extent of unwarranted variations and their implications for patient care in the UK health system.	None – conceptual discussion.	None stated – presentation of examples of variation to exemplify a model of conceptualising UCV.	Bojakowski Model	Hand searching
Bottle, A	2017	UK	To establish the contribution of unwarranted variation in care to regional differences in outcomes observed in patients with thoracic aortic disease in England.	33 studies	Systematic literature review and meta-analysis and survey of cardiac surgical units	None stated – statistical analysis and practice guidelines used to identify UCV.	Hand searching
Dossett, LA	2011	USA	To describe national variation in the use of the prophylactic IVC filter in US trauma centres and whether	Data from the National Trauma Databank 2002-2007 of approximately 2 million de-identified	Retrospective analysis of population-level data.	None stated – controlled for centre level factors to identify UCV and adherence to	Database

			patient or centre factors contributed to variation.	individual records (adults) from more than 770 trauma centres.		guidelines.	
Duckett, S	2015	Australia	To develop a model to measure inappropriate care in Australian hospitals.	Hospital discharge data for 709 public hospitals including 8,720,771 records in financial year 2010-2011.	Secondary analysis of population-level data.	None stated – used existing studies of low value care, no longer appropriate treatments and current national guidelines in Australia and UK.	Database
Fantini, G	2016	Italy	To assess care patterns for persons with schizophrenia against treatment guidelines in Departments of Mental Health (DMHs) and possible organisational and structural reasons accounting for variations between departments.	458 patients with schizophrenia at three Italian DMHs.	Retrospective record review and cross-sectional survey of health professionals.	30 quality of care indicators selected and used as a framework to identify ‘appropriate’ care.	Database
Gani, F	2017	USA	To characterise the variability in inpatient surgical costs, define the factors associated with increased cost and quantitate the	22,559 patients who underwent major surgical procedures by 56 surgeons in 8 subspecialties from 2009-2013 in one	Retrospective analysis of population-level data.	None stated – statistical analysis used to demonstrate variation within and between surgeons, patients and	Database

			variability attributable to patient, surgeon and surgical subspecialty.	tertiary care centre.		specialties and the contribution of each to variation in cost.	
Gauld, R	2011	USA	To assess whether hospitals consider UCV as a problem, the areas in which UCV is of greatest concern and the strategies used to counter UCV.	Five high-performing hospitals explored via 39 interviews with managers and clinical staff forming case studies. 307 chief quality officers from acute hospitals in four US states surveyed.	Case studies using interviews and cross-sectional survey.	Case study sites identified by those areas considered as high-utilisation in the Dartmouth study, survey items regarding possible UCV prevention strategies derived from development by 'expert' panel.'	Database
Graverholt, B	2013	Norway	To a) quantify overall and diagnosis specific variation in acute hospital admission rates among nursing homes and b) to estimate the association between hospitalisation rate and the size, number of short vs long-term beds, ownership status and suburban area.	38 nursing homes in one municipality over a two-year period (Jan 2007- Dec 2008)	Retrospective analysis of admission data for nursing homes.	None stated – statistical analysis to determine the contribution of each factor to variation.	Database
Ibaniz-Beroiz, B	2011	Spain	To apply shared component analysis to	538,358 hospitalisations of	Retrospective analysis of hospital admission	Atlas of Variations in Medical Practice	Database

			model variation in hospital admission rates for chronic disease in elderly males and females.	older adults over 75 years with chronic conditions in 2006	data.	in the Spanish NHS – statistical analysis used to determine the contribution of each factor to variation.	
Karnon, J	2013	Australia	To use risk-adjusted cost-effectiveness to undertake a comparative evaluation of applied clinical practice processes.	4,072,341 records from the Integrated South Australian Activity Collection (ISAAC) reviewed to identify those admitted to ED in one of the four main public hospitals in SA between 2005-2006 with a) principle diagnosis of chest pain or b) with chest pain admission in the previous year.	Retrospective analysis of hospital separation data linked with socioeconomic, cost and all-cause mortality data sets.	None stated - statistical analysis of cost-effectiveness used to determine the contribution of each factor to variation.	Database
Kozhimannil, KB	2014	USA	To examine the extent to which variability in the likelihood of caesarean section was attributable to women's clinical diagnoses.	1,475,457 births in 1,373 hospitals between 2009-2010 from the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project.	Retrospective analysis of hospital discharge data	None stated – statistical analysis to determine the contribution of each factor to variation.	Database
Kunandian, B	2009	USA	To demonstrate that funnel plots can aid	149,888 patients undergoing	Retrospective analysis of the New York PCI	None stated – funnel plots used to	Database

			meaningful interpretation of results regarding variation.	percutaneous coronary intervention (PCI) in 48 hospitals between 2002-2004.	dataset	create upper and lower limits demonstrating unexpected variability in practice.	
Litaker, D	2006	USA	To describe a theoretical approach to develop interventions to improve primary care (by reducing undesirable variation).	Presentation of a conceptual approach no data collection.	Presentation of a conceptual approach no data collection.	Complexity Theory	Database
Mathoulin-Pelissier, S	2012	France	To identify factors associated with practice variation in colorectal cancer care.	1,206 colorectal patients from 53 hospitals in South-West France.	Retrospective medical record review including pathology reports.	None stated-statistical analyses guided by national evidence-based guidelines.	Database
Menon, M	2016	UK	To discuss antecedents of UCV in colorectal cancer clinical pathways and steps to address UCV.	Application of a conceptual approach to colorectal cancer - no data collection.	Application of a conceptual approach to colorectal cancer - no data collection.	Wennberg's UCV definition used.	Database
Mercier, G	2015	France	To assess the geographical variation in potentially avoidable hospitalisations in France, and the determinants of	Data on patients from 96 departments (provinces), 5,590 ZIP codes and 36,000 patients' city-level data.	Retrospective analysis of a range of data sources: national administrative data, the national hospital programme discharge database, the French	Avoidable hospitalisation defined using Weissman et al 1992. UCV identified via statistical analysis.	Database

			potential variation including physician and nurse density.		Ministry of Health, the National Institute for Statistics and Economic Studies, the 2011 Census data and hospital data for each department (province).		
Mercuri, M	2011	Canada	To provide an overview of literature on medical practice variations and of frameworks of UCV.	46 articles that used the term 'unwarranted' in relation to medical practice variation.	Literature review and narrative synthesis	Wennberg's; Sepucha's; Goodmans and Bojakowski's frameworks	Database
McCulloch, P	2013	UK	To understand how unwarranted variations in surgery can be identified and the evidence of the effectiveness of strategies for its reduction.	41 articles regarding interventions in surgery to reduce unwarranted variation – defined as those interventions that modify surgery rates	Literature review and narrative synthesis	None stated	Hand searching
Partington, A	2017	Australia	To identify and assess the burden of UCV in clinical practice.	7950 patients from four hospitals in 2010.	Retrospective analysis of linked routinely collected hospital and mortality data of patients with acute coronary syndromes.	None stated – statistical analysis to determine the burden of UCV.	Database

Runciman, W	2012	Australia	To determine the percentage of health care encounters at which a sample of adult Australians received appropriate care.	1154 Australian adults	Retrospective record review and computer-assisted telephone interviews.	Appropriate care defined as care in line with evidence-based on consensus-based guidelines. 522 expert consensus indicators representing appropriate care for 22 common conditions.	Hand searching
Sheffield, KM	2013	USA	To determine the frequency of potentially inappropriate colonoscopy in Medicare beneficiaries and examine variation between providers and geographic areas.	74,681 (5% of) Medicare beneficiaries in Texas 2000-2009 over 70 receiving colonoscopy.	Retrospective analysis of colonoscopies based on national administrative data.	None stated – practice guidelines used to determine inappropriate care.	Database
Tavender, E	2016	Australia	To apply the Theoretical Domains Framework to explore the factors perceived to influence the uptake of four key evidence-	42 emergency staff (9 Directors, 20 doctors and 13 nurses.	Semi-structured interviews.	Theoretical Domains Framework	Database

			based recommended practices for managing mild traumatic brain injury.				
White, R	2016	Australia	To develop a pain training and educational resource and provide this to patients to enhance knowledge of evidence-informed approaches to challenge practice variations.	No primary data collection – intervention development.	Analysis of impact via YouTube view count across countries in the first three months after the video was launched.	None stated – used evidence-based guidelines to guide content.	Database
Winchester	2014	USA	To explore inappropriate use of myocardial perfusion imaging (MPI).	582 patients undergoing MPI in one medical centre between 2010-2011.	Retrospective medical record review.	None stated – statistical analysis used to determine variations.	Database

Table 2: Summary of included grey articles (n=23)

Author/ organisation	Year	Country	Publication type	Search
Australian Commission for Safety and Quality in Health Care	2016	Australia	Australian Atlas of Healthcare Variation FAQs	Grey
Australian Commission for Safety and Quality in Health Care	2013	Australia	Background paper on medical practice variation	Grey
Australian Commission for Safety and Quality in Health Care	2015	Australia	Report on investigating and addressing UCV	Grey
Australian Commission on Safety and Quality in Health Care and Australian Institute of Health and Welfare.	2014	Australia	Report on OECD study of UCV	Grey
Agency for Clinical Innovation	2017	Australia	Resources from UCV taskforce	Grey
Agency for Clinical Innovation	2017	Australia	Webpage on UCV and ACI approach	Grey
Agency for Clinical Innovation	2016	Australia	Overview of variation in length of stay for prostatectomy in NSW	Grey
Agency for Clinical Innovation	2016	Australia	Overview of variation in stroke	Grey
Agency for Healthcare Research and Quality	2009	US	Presentation on too much prevention in primary care	Grey
Bernal-Delgado, E.	2017	Spain	Presentation on ATLAS VPM	Grey
De Silva, P	2012	OECD member countries	Presentation on RightCare	Grey
Goodman, D.	2012	USA	Presentation on Dartmouth Atlas	Grey
Love, T; Health Quality and Safety Commission New Zealand	2014	New Zealand	Report on analysing and interpreting variation	Grey
Love, T; Health Quality and Safety Commission New Zealand	2014	New Zealand	Literature review of UCV	Grey
National Committee for Quality Assurance	2015	US	Summary of utilisation of	Grey

			frequently performed procedures.	
National Health Service	2013	UK	Report on unwarranted variation programmes	Grey
National Health Service England	2015	UK	RightCare Atlases	Grey
National Health Service RightCare	2017	UK	Report on national data tools to understand and demonstrate variation	Grey
Organisation for Economic Co-operation and Development	2014	OECD member countries	Report on Geographic Variations in Health Care	Grey
Organisation for Economic Co-operation and Development	2014	OECD member countries	Press release on geographic variation report	Grey
Timmins N. The Kings Fund	2017	UK	Getting It Right First Time - review	Grey
UK Government	2017	UK	Press release	Grey
U.S. Department of Health and Health Services	2007	USA	National Healthcare Quality Report	Grey

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