Scoping review and approach to appraisal of interventions intended to involve patients in patient safety

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Objective: To review the literature on the involvement of patients in efforts to promote their own or others’ safety while using health care services.

Method: A total of 1933 reports were identified as potentially relevant and 745 of these were included in the review (437 descriptions of interventions, 299 comment or opinion pieces and 42 discussions or studies of patients’ willingness and ability to adopt safety-promoting behaviours).

Results: The rate of publication on these topics has increased, especially in the USA and UK. However, there is scant evidence of the impact of patient involvement initiatives on safety outcomes and there has been little exploration of patients’ willingness and ability to adopt particular safety-oriented behaviours. We identified three broad routes by which patients’ actions might contribute to their safety by helping to make sure that: their treatment is appropriate for them (informing the management plan); treatment is given as planned and according to appropriate protocols (monitoring and ensuring safe delivery of treatment); and problems and risks within health care systems are identified and reduced (informing systems improvements).

Conclusions: An approach for appraising interventions intended to promote patient involvement in patient safety should involve: identification of the routes by which interventions assume patients’ actions might contribute to their safety; identification of the conditions that would need to be met for patients to behave and contribute as the interventions (implicitly) assume; examination of the extent to which the intervention supports fulfilment of those conditions; and consideration of the potential negative effects of the intervention.

Background
Strategies to reduce adverse events in health care have mainly focused on changing systems of care and professional behaviour. However, more recently there has been growing interest, both in the UK and other countries, in involving patients and or their representatives in efforts to improve safety.

There are a number of ways in which patients might contribute to promoting their own or other’s safety while using health care services. Vincent and Coulter suggest that patients could help to promote their own safety by being involved in reaching an accurate diagnosis; decision-making about treatment; choice of health care provider; making sure that treatment is administered as planned and responding appropriately to adverse events and side-effects.¹ Behaviours relating to these forms of contribution are encouraged by the many books, brochures, posters and tipsheets that have been developed especially in the USA to advise people what they can and should do to avert harm as they use health care services.² However, there is limited understanding of the potential for patients to contribute to their safety, of the acceptability and effectiveness of various interventions which might be used to promote this or of contextual circumstances that might moderate such acceptability and effectiveness.

Aims and objectives of scoping review
We undertook a broad scoping review to identify and critique the various roles and mechanisms by which
patients and their representatives might act to enhance their own or others’ safety as they use health services. We chose a scoping review to facilitate capture of the sense of a broad and disparate literature. The scoping review was used to identify and explore the strategies and/or interventions that have been considered or used with the intention of encouraging patients, and/or their family, to get involved in their care with a view to enhancing their own or others’ safety. In addition we examined literature which described willingness and ability of patients and their family members to adopt safety-promoting behaviours and the circumstances in which they might vary. From this we sought to develop an organizing framework based on the broad routes by which patients’ actions might contribute to their safety.

**Methods**

**Search strategy and selection criteria**

The literature searches were designed to retrieve any reports relating to patient involvement in patient safety. The search strategies were broad and used a comprehensive set of free text terms and subject headings relating to both concepts. These are described in detail in Appendix 1 which is available online at http://jhsrp.rsmjournals.com/cgi/content/full/15/suppl_1/17/DC1. Sources included:

- Databases of systematic reviews, e.g. Cochrane Database of Systematic Reviews;
- Databases of controlled trials, e.g. CENTRAL;
- Health-related databases, e.g. EMBASE;
- Social care databases, e.g. Applied Social Sciences Index and Abstracts (ASSIA);
- Economic evaluation databases, e.g. NHS Economic Evaluations Database;
- Databases of reports, conference proceedings, grey literature, e.g. Dissertation Abstracts, Zetoc Conferences;
- Databases of ongoing research, e.g. Current Controlled Trials;
- Patient safety organizations, e.g. National Patient Safety Foundation; National Patient Safety Agency.

Databases were searched from the date of inception to November 2006. No study design or language restrictions were imposed.

**Selection of studies and data extraction**

Two authors (MP and JH) screened citations of titles and abstracts for potentially relevant papers. The inclusion criteria were then applied (based on the full paper). Reports included were those which reported either:

- roles or mechanisms by which patients and their family members may act intentionally or unintentionally to enhance their own or others’ safety;
- reports of the willingness of patients and their family members to adopt these roles or the ways these roles have been adopted in practice.

Agreement between reviewers was checked through joint assessment of a selection of publications. Any disparities or uncertainties about inclusion were discussed with a third researcher involved in the project (YB). Publications were initially grouped according to whether they contained:

- descriptions of interventions intended to promote the contribution of patients’ or family members to patient safety (with or without evaluation of effectiveness);
- comment or opinion about patient involvement in patient safety;
- information relating to patients’ willingness and ability to adopt safety-oriented behaviours.

**Results**

The search strategy produced over 13,700 bibliographic records. The initial screening of these identified 1933 publications as potentially relevant and full copies of these were ordered. The assessment of the full text of these 1933 publications resulted in 745 of these being included in the scoping review (Figure 1, Appendix 2 – available online at http://jhsrp.rsmjournals.com/cgi/content/full/15/suppl_1/17/DC2).

**Overall description of literature included in the scoping review**

**Country of origin**

As expected, a large proportion of the review literature derived from the United States (US) (512 out of 745 included publications). Other reports were from the United Kingdom (113); Australia (19); France (16) and the Netherlands (14). Reports from 24 other countries were reviewed including several written by multinational collaborators. Thirty-two publications in a language other than English were screened and 28 were included in the review.

**Overview of ‘intervention’ literature**

A total of 437 publications described one or more interventions to promote patient contributions to patient safety. Very few provided an explicit rationale for the interventions they described or outlined the theoretical
underpinnings of their approaches. Some of the reports of interventions that did include reference to theory hypothesized that the benefits associated with patient involvement in disease specific quality improvement and treatment decision-making would be repeated in the context of safety-oriented initiatives.4,5 There has been little patient involvement in the development of some of the high-profile interventions and few interventions have been formally evaluated.2 The few that have been formally evaluated are considered in detail in a linked systematic review.6

Overview of ‘commentary’ literature

The 299 publications classified as commentaries and opinion pieces provide useful insight into the development of interventions. Grouping the commentaries chronologically revealed increasing recognition, over the years, of the complexity of patient safety problems and a corresponding increase in sophistication of the responses to these problems. For example, some early interventions sought simply to increase patients’ knowledge about their medication in line with professional assumptions about what patients need to know to increase their compliance with the prescribed regimes. More recent publications focused on the danger of designing interventions intended to involve patients in promoting their own safety without understanding patients’ perspectives on treatments and health care provision.7

Overview of literature relating to patients’ willingness and ability to adopt safety-oriented behaviours

Forty-two reports explored the willingness and ability of patients to adopt explicitly safety-oriented behaviours while using health services. These could be classified into four broad groups:
personal experience of and reflection on adopting safety behaviours;
expert commentary on the barriers and facilitators to, and concerns about, patient involvement in promoting their own safety;
qualitative exploration of patients’ and family members’ experiences of adopting safety behaviours for patients and their representatives;
surveys of patients which explore willingness to adopt safety behaviours.

Organizing framework

Using the literature identified in the scoping review we developed a framework for organizing the literature which is based on three broad routes (each with several subroutes or pathways) by which patients’ actions might contribute to their safety. These are presented in Box 1 with illustrative examples from the literature.

The means by which interventions were intended to enable patients to contribute to their safety were not always made clear in the published descriptions. This was important to consider when categorizing behaviours and interventions.

Some of the interventions identified in the review may promote patients’ contributions to safety via more than one of the above routes and pathways. For example, a patient treatment diary could support informing the management plan if patients recorded information relating to their medical history, concurrent conditions, allergies and responses (including adverse reactions) to medication and shared this diarised information with their health care professionals. The diary could be categorized as supporting monitoring and ensuring safe delivery of treatment if it: (a) enabled patients to check care was being delivered as planned because it contained general information about warning signs and symptoms to look out for, or about the kinds of tests that were recommended; or (b) encouraged patient record-keeping that facilitated professional or personal monitoring of care delivery and responses.

Willingness and ability of patients to adopt safety-oriented behaviours

The small amount of literature that explored the willingness and ability of patients to adopt recommended safety-promoting behaviours points to what might be considered facilitators and barriers to patient involvement in safety promotion. It largely reflects concerns that, although patients appear to be ideally placed to act to keep themselves safe, there are a number of factors that can make this problematic: (a) the varied characteristics of individual patients including knowledge and health status which can affect their ability to act in particular health contexts; (b) patient experience of and beliefs relating to medical error; (c) patient preference for collaborative rather than confrontational behaviours; and (d) the anticipated and actual response of health professionals to patients’ efforts to contribute to their care and safety. We summarize the key insights from this literature using the framework outlined above and illustrative examples of interventions from the literature reviewed, including recommendations from safety advisories that are given to patients.

We then use the organizing framework and insights from the literature relating to patients’ willingness and ability to adopt safety promoting behaviours to develop an outline approach to appraising interventions to promote patient involvement in patient safety. This is intended to help clarify and facilitate a more precise and critical discussion about the various forms of patient involvement in patient safety and the appropriateness and feasibility in different situations.

Informing the management plan

By sharing all relevant information with the health professionals involved in formulating plans

This seems to be a behaviour which many patients recognize as part of their role. US consumers surveyed about health quality and safety by AHRQ and Kaiser

Box 1 Organizing framework for interventions intended to involve patients in patient safety

Informing the management plan
Helping to ensure the appropriate treatment plans are formulated by:
• sharing relevant information with the health professionals involved in formulating plans, e.g. by making sure that health care professionals know about any allergies or adverse reactions to medication;
• making sure that a proposed plan is appropriate, e.g. by asking if there are any alternatives to the treatment recommended.

Monitoring and ensuring safe delivery of treatment
Helping to ensure that patient treatment is given as planned, and correctly by:
• helping to ensure safe delivery of planned treatment by health professionals, e.g. by checking on a chemotherapy calendar that the correct dose of medication is given at the right time;
• helping to ensure safe delivery of treatment by self, e.g. by monitoring blood INR levels and modifying self-administered anticoagulant medication dose in response to this;
• acting to minimize any potential problems of treatment and responding appropriately if they occur, e.g. by following instructions for self-care after surgery and contacting the surgical team if any notifiable symptoms occur.

Informing systems improvement
Helping to ensure that problems and risks within health care systems are identified and reduced by:
• providing feedback about experiences of health quality and safety, e.g. by completing a post-discharge survey;
• acting as a patient representative, e.g. by serving on a patient and family advisory council to identify and appraise possible safety improvements.
Family Foundation in 2004 and again in 2006 indicated in the latter survey that they were increasingly volunteering information about allergies and adverse reactions even when not asked to do so by health professionals. However, there may be reasons why patients do not share even what they know to be relevant information with health professionals. These might range from difficulty or discomfort with communication to reluctance for details such as illegal drug use or problems with alcohol to be documented on a medical record which might be accessed by employers or social services.

By making sure that a proposed plan is appropriate

This not only requires patients to understand the treatment which is planned for them and alternative tests/treatments which might be available but also to then make a decision about whether or not it is needed. One patient commentator described in some detail her experiences of ‘partnering’ with health professionals. Some of the health professionals she worked with were happy to answer the questions she asked to make sure that the treatment they proposed was right for her but others were not. She continued to consult with those willing to work with her to come up with a plan with which they were both comfortable, but stopped consulting with the others. Not all patients have opportunities to switch between care professionals and many are uncomfortable about adopting questioning behaviours which potentially challenge or appear to challenge health professionals’ judgement.

Monitoring and ensuring safe delivery of treatment

By helping to ensure safe delivery of planned treatment by health professionals

A significant proportion of patients are likely to find the suggestion that they ‘check’ what health professionals do problematic. In many contexts this will seem to involve challenging health professionals’ practice and, perhaps, imply a lack of trust that patients do not wish to convey. Asking practitioners if they have washed their hands is a role which has been identified for patients, but many patients said they would not ask and those who say they would ask can find it difficult in practice. Patients may be concerned about the ramifications of their actions for their own treatment or, in the case of parents or carers, for their child or relative.

By helping to ensure safe delivery of treatment by self

In general, most people find the self-administration of most kinds of medication feasible, and they value interventions that aim to educate and support them to do so safely and confidently. Engaging in efforts to deliver and monitor one’s own treatment is, especially if facilitated by health professionals, a collaborative rather than confrontational behaviour, and one that patients, generally, find acceptable.

By acting to minimize any potential problems of treatment, and responding appropriately if they occur

This relies on patients having access to and understanding information about the potential adverse effects of medication and treatment, what to seek advice about and, if this is necessary, how to get access to this advice. Even if this process is unproblematic – the patient understands the advice, recognizes the symptoms, rings for advice and receives it – there may be other reasons why a patient may choose not to respond appropriately. He/she might be, for example, reluctant to report adverse effects of a medication after not complying with treatment instructions.

Informing systems improvements

By feeding back individual experience of health quality and safety

Many patients appear to be happy to be involved to be asked to contribute to health care quality and safety by participating in feedback surveys if they believe these will make a difference. However, they may be reluctant to be involved in more time-consuming ways.

By acting as a patient representative

When patients are asked to act as representatives on, for example, hospital design groups or safety committees, they are generally expected to do so within the existing system. Additionally their involvement is facilitated by health care professionals or managers who operate within that system. Some consumer representatives have found this constraining because, for example, the definitions of safety and quality used by the committee are narrower than their own. Without being given scope to redefine these concepts they cannot effectively bring their consumer perspective to the development and improvement of services.

All of the above behaviours to a greater or lesser degree require patients and their representatives to be well-informed, about their own health circumstances and about standard protocols and procedures which may govern or impact on their treatment. The capacity to do this varies between individuals and has been found to be affected by achieved educational level, income, cognitive skills and cultural differences which...
may affect patients’ health beliefs and their ability to fully utilize health services.\textsuperscript{10,12,15,16,19–21}

Using the organizing framework to appraise interventions

In order to demonstrate how the framework might be used to help examine strategies intended to involve patients in promoting safety, two interventions are now ‘unpicked’. To do this we have combined the description of the interventions with information from the review about patients’ willingness and ability to adopt patient safety promoting behaviours. Mindful of the concerns about lack of theory behind many interventions we follow Greenhalgh et al.\textsuperscript{22} and draw attention to the intended outcomes of interventions, the mechanisms by which they are (apparently) intended to work and the ‘implicit assumptions’ that must be fulfilled if the intended outcomes are to be achieved.\textsuperscript{22}

To appraise an intervention we suggest the following approach:

- identification of the ‘route(s)’ by which the intervention assumes patient behaviours might enhance patient safety;
- identification of conditions that would need to be met for the patient to adopt the behaviours and make an effective contribution (this includes conditions relating to the patient and their family, the health professionals involved in their care, and the health care organization/systems within which care occurs);
- examination of the support offered by the intervention and consideration of whether and to what extent it would ensure that the necessary conditions could be fulfilled (this is a context dependent examination);
- consideration of the potential negative effects of the intervention.

This is illustrated in Boxes 2 and 3.

Discussion

Where this scoping review fits

This review represents an attempt to scope and describe the large amount of literature about patient involvement in patient safety. Most related reviews have critiqued patient safety literature more widely although some have a chapter or section about patient involvement.\textsuperscript{4,24} Others, while being focused on patient involvement have been more limited in their scope.\textsuperscript{25,26} Overall conclusions appear to be largely similar to this review – evidence for the effectiveness of recommended safety-related behaviours is lacking, generally, patients have not been involved in the development of interventions and we know very little about patients’ willingness and ability to adopt recommended patient safety promoting behaviours.\textsuperscript{2,4} However, this review, as well as describing the literature has developed a framework that encourages an analysis of interventions according to the ways in which they envisage patients contributing to their safety and the assumptions they make about patients’ willingness and ability to act. This analysis facilitates identification of the appropriateness of the support offered by interventions to enable patients to contribute effectively. This builds on the work of Vincent and Coulter\textsuperscript{1} and Koutantji et al.\textsuperscript{24} who identified roles for patients in promoting safety and Davis et al.\textsuperscript{26,27} who explored and categorized the factors which influence patient participation in patient safety and the willingness of patients to question staff on quality and safety issues. This review goes further in

<table>
<thead>
<tr>
<th>Box 2</th>
<th>Example of an appraisal of a patient safety intervention intended to involve patients</th>
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<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td>Patients beginning a course of chemotherapy are given a calendar to track their treatment and check that the right medication and total dose are given.\textsuperscript{23}</td>
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<td><strong>This intervention is intended to prompt patients to help ensure the safe delivery of treatment by health professionals.</strong></td>
<td>The conditions to be met for patient contributions to be effective include:</td>
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<td></td>
<td>• that the patient is capable of knowing and is well-informed about what the plan is (medication and dosing schedule) and how it should be implemented (dose delivery plan);</td>
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<td></td>
<td>• that the patient can detect deviations from the plan;</td>
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<td></td>
<td>• that the patient will speak up if there is any deviation from the plan;</td>
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<tr>
<td></td>
<td>• that health professionals will respond appropriately if the patient speaks up.</td>
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<tr>
<td><strong>Questioning the support provided by the intervention</strong></td>
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<tr>
<td></td>
<td>• Is the information about the plan delivered in a form the patient can understand? Patients capacity to take on information varies between individuals and at different times on the patient journey.</td>
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<td></td>
<td>• Interventions which include information giving are rarely tailored to individual patient needs and there is little indication in the literature reviewed of awareness of the need to check understanding.</td>
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<td></td>
<td>• Patients may just not understand the information they are given and may not feel well-informed enough to take any safety action. However, this intervention does involve face-to-face education by a pharmacist which has the potential to be individualized and reinforced if necessary.</td>
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<td></td>
<td>• Can patients access and understand the information needed to monitor treatment delivery? Checking the dose and type of chemotherapy administered should involve checking of the label on the medicatin, whether intravenous or oral, and the medication chart. These items are professional tools and patients may feel they need permission from health professionals before doing this.</td>
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<td></td>
<td>• Do staff provide opportunities for the patient to voice concerns? Speaking up could be perceived by patients as challenging the professionalism of staff so this is likely to be problematic for patients. The giving of a chemotherapy calendar may be perceived as permission to act by both patients and staff.</td>
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<tr>
<td><strong>Potential negative effects of the intervention</strong></td>
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<td></td>
<td>• If patients do not feel capable of performing this role either because they lack the ability or confidence to do it or they are not well today and they do not have access to an advocate this may cause unnecessary anxiety.</td>
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</table>
We are not aware of any literature that would change the conditions to be met for patient contributions to be effective are:

- the patient is capable of deciding what is relevant information;
- that the patient will share this information with all prescribers;
- that health professionals will encourage (or not discourage) patients from volunteering information;
- the health professionals will respond appropriately if the patient volunteers information.

Questioning the support provided by the intervention

- Is information about the relevance of information provided? Patient and professional understanding about what is relevant information may differ. Patients may not consider that taking of herbal medication or dietary supplements is relevant to a prescriber or that it could be classified as 'medication'. They may believe that a past adverse reaction to a medication was caused by them not following instructions properly or that health professionals will disapprove of them taking 'alternative' treatments.
- Will the health professional facilitate patient involvement by encouraging or not discouraging their contribution and responding appropriately if the patient volunteers information? Tipsheets, unless they are part of an organizational strategy to stimulate patient involvement which includes encouraging health professionals to act as facilitators, do not provide support for this aspect of the intervention. Patients do not know how health professionals will respond to their input. We know that patients will share information if prompted by are also easily discouraged by perceived or actual health professional response.

Potential negative effects of the intervention

- Patients may worry about what is relevant information especially if they are not given the opportunity to share what they feel is relevant with health professionals.
- If patients do not feel willing able or well enough to perform this role today this may cause unnecessary anxiety.

terms of unpacking the mechanisms by which patient involvement might enhance patient safety and identifying the broader conditions that may be necessary to ensure these can be effective.

Strengths and limitations

The search may have missed studies which describe involvement interventions where safety has been improved but where safety improvement was not the primary, or stated aim of the intervention. This might especially be the case with older publications at a time when the term ‘patient safety’ was less frequently used.

Publications have not been excluded on grounds of quality and peer-reviewed publications sit alongside self-help guides to ‘survive your hospital stay’. This was necessary to gain a wider sense of the movement to involve patients in patient safety, much of which has involved disparate, ‘common sense’ responses adopted by individual organizations or in particular areas.

A large part of this literature originated in the United States. Its applicability in other countries may be limited. However, the range of interventions described from different countries with different health care systems illustrate that similar approaches are being adopted within them. The practitioner–patient relationship appears to have key similarities worldwide. This includes a knowledge and status imbalance which means that the ability of a patient to adopt safety-related behaviours is profoundly affected by their own capacity to access and use knowledge and health professionals’ response to their taking on this role. The framework and analytical approach developed here should facilitate the consideration of these issues in relation to particular contexts and so be helpful to those considering transferring patient involvement strategies to different settings.

Possible negative effects of patient involvement

The literature reviewed reveals little exploration of the potential negative effects of patient involvement in promotion of their own or other’s safety. The few papers that have considered these suggest some strategies to involve patients may: impact negatively on relationships between health professionals and patients; halt or limit other safety strategies; increase anxiety for patients and unfairly transfer responsibility for safety onto patients. Such strategies may also disproportionately burden already disadvantaged patients. Calls for patients to take on some of the responsibility for their safety while using health care services does not appear to take into account the variability in the condition of the patient throughout a treatment journey, the capacity of patients and their carers to adopt safety promoting behaviours and the potential for negative responses from health professionals if patients or their representatives do express concerns. Use of the framework and analytical approach developed should facilitate identification and consideration of these potential negative effects and ways that they might be avoided.
Further research

Many patient involvement safety strategies are already being implemented, often in a piecemeal fashion with different interventions being implemented simultaneously. The complex nature of health care makes separating safety from other outcomes problematic. However, rigorous evaluations of interventions are needed. There are a range of study designs to choose from, both experimental and non-experimental. Several commentators have engaged with this topic, suggesting possible avenues of investigation. Our framework should help to identify promising approaches before large scale evaluations are carried out.

Conclusion

A large volume of literature has been generated by the huge interest in the potential for involving patients in promoting their own and others’ safety. This involvement has widely been seen as desirable and potentially beneficial based on experience of patient involvement in decisions about their care and chronic disease management. There also appears to be an assumption that indication of willingness to participate or adoption of safety-related behaviours by some patients means that all patients will be prepared and/or able to do the same. Few of the interventions have been evaluated for effectiveness or acceptability, many appear to be ‘knee-jerk’ reactions to adverse events and their theoretical basis has not been established. There appears to have been little consideration of the mechanism of effect and of what conditions and circumstances are required for patients to adopt safety roles, including their willingness and ability to do so. In addition there has been little exploration of the potential negative effects of patients’ involvement in promoting their own safety.

We might conclude that there are some ways that patients might effectively be involved in keeping themselves safe while using health services and that patient involvement in their wider care is desirable. The approach we have developed on the basis of this scoping review encourages attention to the mechanisms by which patients might contribute to their safety, the conditions under which their contributions are likely to be successful and the extent to which these interventions are likely to ensure those conditions are filled in particular contexts. This approach should facilitate consideration of how and how well existing and future interventions might support patients’ contributions to patient safety in different contexts.

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