Health Policy Analysis

Financial Risk-Sharing in Updating the National List of Health Services in Israel: Stakeholders’ Perceived Interests

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ABSTRACT

Objectives: Risk-sharing is being considered by many health care systems to address the financial risk associated with the adoption of new technologies. We explored major stakeholders’ views toward the potential implementation of a financial risk-sharing mechanism regarding budget-impact estimates for adding new technologies to the Israeli National List of Health Services. According to our proposed scheme, health plans will be partially compensated by technology sponsors if the actual use of a technology is substantially higher than what was projected and health plans will refund the government for budgets that were not fully utilized. Methods: By using a semi-structured protocol, we interviewed major stakeholders involved in the process of updating the National List of Health Services (N = 31). We inquired into participants’ views toward our proposed risk-sharing mechanism, whether the proposed scheme would achieve its purpose, its feasibility of implementation, and their opinion on the other stakeholders’ incentives. Results: Participants’ considerations were classified into four main areas: financial, administrative/management, impact on patients’ health, and influence on public image. Most participants agreed that the conceptual risk-sharing scheme will improve the accuracy of early budget estimates and were in favor of the proposed scheme, although Ministry of Finance officials tended to object to it. Conclusions: The successful implementation of risk-sharing schemes depends mainly on their perception as a win-win situation by all stakeholders. The perception exposed by our participants that risk-sharing can be a tool for improving the accuracy of early budget-impact estimates and the challenges pointed by them are relevant to other health care systems also and should be considered when implementing similar schemes. Keywords: budget-impact, reimbursement, risk-sharing.

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Introduction

Innovative health technologies pose a substantial financial burden on insurers, patients, and health care systems worldwide. As a result, several countries have established agencies to determine what technologies provide good value and should be covered. In response to patients’ and clinicians’ pressure on governments and reimbursement authorities to accelerate access to new and innovative technologies, despite significant uncertainties surrounding their effectiveness and the budget impact at the time of introduction, several health care systems have recently implemented various novel approaches, such as “risk-sharing” mechanisms, to manage these uncertainties. To balance the technology sponsor’s desire for early market access with the necessity to ensure effective and efficient use of limited health care resources, some of the financial risks involved are shifted from the payer to the technology sponsor. So far, technologies that have been covered under such agreements have tended to be for severe indications with great unmet need, substantial uncertainty about long-term safety and effectiveness, high cost/budgetary impact, or strong political/patient lobby demanding access [1].

Adamski et al. [2] suggest two sub-categories of risk-sharing agreements: performance-based and financial-based. Performance-based contracts focus on the efficacy of the product and are designed to ensure that the intervention results in the promised health improvement. When a pre-specified outcome is not reached, the cost of the technology is partially or fully reimbursed to the payer. Financial-based risk-sharing agreements, either price-volume agreements or patient access schemes, focus on controlling the financial impact of introducing a new technology and aim to reduce the budget-impact uncertainty that is frequently associated with coverage and reimbursement decisions. In a typical case, when the total budget impact or the amount paid for treating a single patient exceeds the target that the technology sponsor and the payer agreed upon, then the technology sponsor is required to reimburse the payer. McCabe et al. [3] suggest that these schemes may be relevant when there is a considerable uncertainty about the size of the population that will benefit from the technology. Com-
The Process of Updating the National List of Health Services in the Israeli Health Care System

The health care system in Israel operates under a National Health Insurance Law where health care is provided by four competing, not-for-profit health plans. The government allocates the health budget to the health plans who are obliged to ensure that their members have access to a benefits package that includes inpatient services, ambulatory care, pharmaceuticals, and other technologies (National List of Health Services [NLHS]) [12,13]. Every year since 1998, as part of the annual budgeting process, the government determines the budget that will be available to fund new technologies to be added to the NLHS. Each NLHS updating cycle starts with a call for proposals published at the beginning of the calendar year by the Ministry of Health (MOH). The pharmaceutical and medical device companies or their local distributors (the technology sponsors) are then required to submit a formal dossier providing details on the efficacy of the proposed technologies as well as the projected annual budget needed to fund them. More recently, a cost-effectiveness analysis presenting a cost per quality-adjusted life-year ratio is required for proposed technologies associated with annual costs above 100,000 Shekels (approximately US$30,000) per patient.

The recommendations on which new technologies should be added to the NLHS are made by an ad hoc Public National Advisory Committee (PNAC). The PNAC currently includes senior officials from the MOH, the Ministry of Finance (MOF), the health plans, and representatives of the public at large. The PNAC evaluates all proposed technologies and considers clinical, economic, social, and ethical aspects when making coverage decisions. This process is unique, as all candidate technologies considered for coverage compete with each other for funding. Various aspects of the process of updating the NLHS have been described and scrutinized elsewhere [14–22].

Because of the budget constraint, the estimated budget impact of each technology plays a major role in coverage decisions. A subcommittee of representatives from the MOF, the MOH, and the four health plans provides the PNAC with the anticipated budget impact of each technology considered. The subcommittee’s figures take into account the budget projections that were provided by the technology sponsors in the formal dossiers, medical experts’ opinion, and independent projections provided by the health plans.

Resources allocated annually to health plans for providing the new technologies remain constant over the subsequent years. Thus, health plans face a considerable financial risk if the utilization is substantially higher than what was projected at the time of listing. In contrast, when the technology utilization is lower than what was initially forecasted, the budget saved may be used by health plans for other purposes.

The two major stakeholders involved in the process of updating the NLHS may perceive contradicting incentives. Health plans that face a financial risk if the actual demand exceeds the early utilization projections are incentivized to overestimate the budget required to minimize their financial risk once the technology is reimbursed. In contrast, technology sponsors that are motivated to receive coverage for their technologies may incorporate in their dossier submissions conservative estimates on the number of potential users of the new technology and the future budget impact, thus improving the chances for the technology to be included in the NLHS. Then, once the new technology is covered, extensive marketing efforts on the part of technology sponsors will expand the demand and increase the number of treated patients, rendering the allocated budget insufficient.

In a previous article [15], we outlined a conceptual framework for a financial risk-sharing mechanism between the Israeli health plans, the government, and the technology sponsors to hedge against uncertainty in the total budget required for the coverage of the new technologies. According to this mechanism, health plans will be partially compensated by the sponsors if the actual use of the new technology is substantially higher than what was projected. On the other hand, health plans will partially return funds to the government if the amount of the newly listed technology utilized is significantly lower than the early estimates. The refunded budget will then be reallocated and used for adding additional technologies to the NLHS in the subsequent updating cycles. The proposed scheme is not a simple price-volume agreement, because it suggests that in cases in which the utilization of the technology is lower than the early estimates, the health plans (“the payer”) will need to refund the government for unused budgets. We assumed that this risk-sharing model would motivate both technology sponsors and health care providers to provide more accurate budget-impact estimates to minimize their potential financial risk.

In our current study, we explored the views and concerns of the main stakeholders involved in the NLHS updating process toward possible implementation of the proposed risk-sharing mechanism and whether they believed that it would result in a more accurate budget-impact forecasting, as we hypothesized. We discuss advantages and disadvantages associated with the adoption of the proposed risk-sharing arrangement as viewed by the stakeholders themselves and by their counterparts.

Methods

We used a semistructured interview protocol to conduct interviews with major stakeholders involved in the process of updating the NLHS and with leading health policy academic researchers. All potential interviewees contacted agreed to participate. The interviews were conducted in the period between January 2008 and April 2010. Participants included 10 government officials, 8 senior managers in the country’s four health plans, 7 pharmaceutical industry executives, 5 academic researchers, and 1 representative of the Israeli Medical Association. Government officials interviewed included representatives from the MOH and the MOF, who play a major role in planning and controlling the health care system. Among all participants, nine were physicians, eight were registered pharmacists, eight others were economists, and the reminder had other training. The majority of participants (25 of 31; 81%) were men.

Government and health plans officials were chosen because they were all current or former members of the PNAC or the PNAC subcommittee, and so were directly involved in the updating process of the NLHS. We approached pharmaceutical company executives who represented the companies with the highest volume of sales in Israel that presumably have the largest impact on the Israeli pharmaceutical market. Health policy scholars were selected on the basis of their research interest in health economics, health technology assessment, and evaluating the process of updating the NLHS in Israel. We also interviewed one official from the Israel Medical Association. However, because the Israel Medical Association decided during the interview period to withdraw from the PNAC deliberations, we excluded this interview from our final analysis.

We inquired into the interviewee’s views toward our proposed risk-sharing mechanism: whether the proposed scheme would achieve its purpose, its chances for improving patients’ health status, feasibility of its implementation, and their opinion on the other stakeholders’ incentives to accept or to object to it. All interviews were conducted face to face by the lead author (A.H.) in the participants’ offices and lasted between 40 and 90 minutes. Subsequent to receiving an explicit consent, the interviews were audio recorded and transcribed verbatim. Detailed field notes were written during and immediately after the interviews. The open-ended questions asked and analyzed in our current study are presented in Appendix A in Supplemental Materials found at doi:10.1016/j.jval.2012.01.007.
Table 1 – Health plans’ considerations in favor of and against the proposed risk-sharing mechanism.

<table>
<thead>
<tr>
<th>Considerations in favor of the risk-sharing mechanism</th>
<th>Considerations against the risk-sharing mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial considerations</td>
<td>None</td>
</tr>
<tr>
<td>Patients’ health considerations</td>
<td>None</td>
</tr>
</tbody>
</table>

We began the analysis by immersing in data [23] through repeated readings of the verbatim transcriptions and interview notes. Then, detailed descriptions of each interviewee’s views were produced. Last, by using the constant comparison method [24], we synthesized analysis across participants. The trustworthiness of the study was ensured mainly by using three strategies: purposive sampling of interviewees allowed maximal range of stakeholder’s views. Reflexibility was reached by using field notes and thick descriptions of each participant and his or her views. The participants’ views were classified during peer debriefing sessions among two of the authors (A.H. and D.G.).

Results

We first asked participants to describe their own considerations in deciding whether to support the proposed risk-sharing framework and then we explored what they believed the other stakeholders’ motivations would be. Participants’ considerations were classified into four main areas: financial issues, administrative/managerial matters, possible impact on patients’ health, and influence on public image (Tables 1–3). Among health plans’ executives (Table 1), the vast majority of considerations expressed were financial. There was a consensus that the new mechanism would improve the budgetary balance of the health plans, and so, all health plans’ executives supported possible adoption of the risk-sharing mechanism. Typical comments expressed by health plans’ executives were as follows:

If I get compensated for excessive use of technologies, I’ll be willing to return any unused budget. (Health plans 6)

The health plans are not seeking to make profits from the technology budgets; all they want is to receive a realistic budget in order to provide patients’ health needs. (Health plans 3)

The majority of the other stakeholders also believed that the health plans would support the proposed framework, although two government officials and two academics suggested that the health plans’ executives would oppose the mechanism. They presumed that the health plans would prefer the current practice in which unused budgets are maintained and used by the health plans for other purposes and not returned to the governmental budget. One of the academic scholars explained:

The health plans are currently profitable in their technology budgets. The question is not only whether the proposed mechanism is efficient, it is also the status at which you are entering it. (Academia 4)

Pharmaceutical industry executives mostly supported the conceptual risk-sharing framework. Their support was motivated by financial and administrative incentives and also by a desire to enhance their public image as contributors to improving population’s health (Table 2).

The proposed scheme will lessen the financial strain from the health plans in adopting new technologies. The technology

Table 2 – Technology sponsors’ considerations in favor of and against the proposed risk-sharing mechanism.

<table>
<thead>
<tr>
<th>Considerations in favor of the risk-sharing mechanism</th>
<th>Considerations against the risk-sharing mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial considerations</td>
<td>The industry can’t be accountable for prescribing decisions made by the physicians.</td>
</tr>
<tr>
<td>Administrative considerations</td>
<td>In the proposed mechanism, the risk is only to the industry. The health plans will always get the new technologies budget in one way or another.</td>
</tr>
<tr>
<td>Public image considerations</td>
<td>Companies with a short pipeline will not benefit from other technologies added to the NLHS from budgets returned by the health plans</td>
</tr>
</tbody>
</table>

NHLS, National List of Health Services.
The scenario that I am afraid of is that if, as a result of implementing the risk-sharing scheme, we will discover that there is a real overutilization of the technology, there will be a demand from the government to compensate the health plans with extra funds. (MOF 1)

The government is not a good negotiator with the health plans and the pharmaceutical companies on retrospective reimbursement. Additional bureaucracy would hurt everyone. There will be an insanity of reimbursement and mutual claims. (MOF 1)

Their counterparts in the MOH usually supported the scheme, but they believed the pharmaceutical industry will object to this agreement. The pros from the MOH view were financial and administrative, but they also related to the possible improvement in patients’ health status (Table 3):

The MOH’s interest is that the NLHS will be as broad as possible. (MOH 4)

If one can expand the NLHS, without increasing the resources—then why not be supportive? (MOH 6)

The interviewees responded also to three questions regarding the theoretical benefits of actually adopting the risk-sharing scheme and whether it would be possible to implement such a mechanism. Most participants thought that the mechanism would be beneficial if implemented and would indeed improve the accuracy of early budget-impact estimations, but there was a lot of skepticism on whether it can actually work out (Table 4).

A number of interviewees pointed out the low level of trust among the different stakeholders as a major obstacle in the possible implementation of the proposed framework. This concern was expressed by all stakeholders. For example, technology sponsors suggested the following:

Although the world is starting to get used to risk-sharing schemes, implementing such a mechanism will require a high grade of trust among all stakeholders, which currently is not the situation in Israel. (Sponsors 6)

Similar concerns were expressed by participants from the MOF, academia, and health plans:

At this time, the level of trust within the health system is terrible; I do not see how it can work. (MOF 1)

The necessary condition for the government to agree to implement such a mechanism is that they will have full access to all technology consumption data. Otherwise they will be afraid of “deals” between the health plans and the technology sponsors. (Academia 1)

| Table 3 – Government officials’ considerations in favor of and against the proposed risk-sharing mechanism. |
|---------------------------------------------------------------|---------------------------------------------------------------|
| Considerations in favor of the risk-sharing mechanism | Considerations against the risk-sharing mechanism |
| Financial considerations | The risk-sharing agreement bears no risk on the government. The agreement will bring a more rational use of the health budget. If unused budgets will be returned by the health plans and used for other technologies, the health system will produce more quality-adjusted life-years for the same funds. The agreement will lead to more accuracy in early estimates of the technology’s budget impact. |
| | There is an indirect risk on the government. If it is known that the actual use of the new technology is significantly higher than projected, there will be a demand to the government to allocate extra funds. The agreement might allow manipulations between the health plans and the industry against the government. The scheme will actually be “cream sharing” and not “risk-sharing.” |
| Administrative considerations | The mechanism will create more transparency on technology utilization in the health care system |
| | The agreement will change the status quo in the system. The mechanism is now in a reasonable equilibrium; why introduce “noise” in the system? The regulator does not know how and is unwilling to deal technically with such mechanisms. Enforcing refunds will create an accounting bureaucracy. |
| Patients’ health considerations | It will be possible to reimburse more technologies with the same allocated budget, which will improve patients’ health. |
| | None |

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technology sponsors, became supportive toward exploring the ac-
gies. On the other hand, the technology sponsors’ support for the
health plans’ support was quite obvious to most participants
The concept of risk-sharing scheme would indeed improve early bud-
literature publications. To the best of our knowledge, stakeholders’
though this information was sparse and mainly represented “gray”
potential to facilitate patient access to promising new technologies
payers) seemed to share the view that these schemes offer the
“access with evidence development” schemes. They found that all
stakeholders (e.g., technology sponsors, patients, providers, and
industry. The main sponsors’ considerations in supporting the
as a sticking point and as such were beyond the scope of the current
study; “to keep it simple,” the health plans are not required to refund
the government if the actual number of patients will be lower than
projected.

Our conceptual risk-sharing proposal was presented to the de-
cision-makers in the MOH and the MOF as part of the interviewing
process but as to date (October 2011), government officials have
not decided yet whether further schemes will be suggested and
implemented and, if yes, what would be the exact mechanism.

Our study has several limitations that relate mainly to the se-
lection of participants. We used a purposive sampling technique
to approach various stakeholders that have a vast interest in the
process of updating the NLHS in Israel. Among technology spon-
sors, we chose to interview those representing the largest phar-
aceutical companies in Israel, because we believed that these
technology sponsors have the largest impact on the pharmaceu-
tical market in Israel. Although these executives were supportive
of our proposed risk-sharing mechanism, it is possible that man-
gers of smaller pharmaceutical companies would have expressed
different opinions than those revealed in our study. Nevertheless,
because we did not observe a substantial variability in responses
of participants from the various pharmaceutical companies, we
believe that their views may be representative of the entire indus-
try in Israel. Moreover, we did not interview executives from med-
ic device companies, because the vast majority of technologies
considered for inclusion in the NLHS are pharmaceuticals. We also
did not approach patient advocate groups; although patients may
benefit from risk-sharing agreement, their current influence on
decisions made by the PNAC is very limited.

Another limitation of the current study is that we did not pres-
explicitly the mechanism in detail; what are the stakeholders’
tolerance limits? What level of use would constitute overuse or
underuse that would trigger a payment on the part of the sponsor,
or a rebate by health plans? How much should be the rebate? It is
also conceivable that technology sponsors may seek different tol-
erance levels for their different products. These issues may well be
a sticking point and as such were beyond the scope of the current
study. To address these and other issues that rose from our qual-
itative analysis, we are currently exploring a mathematical model
using a game theory approach that may provide more quantitative
answers to some of these concerns.

Notwithstanding these limitations, we believe that our study
is the first to shed light on stakeholders’ opinions on a potential
risk-sharing agreement meant to improve the accuracy of bud-
g-impact estimations. Furthermore, our analysis has some
important policy implications; Our study revealed that most

<table>
<thead>
<tr>
<th>Table 4 – Additional feasibility questions.</th>
<th>Health plans</th>
<th>Government</th>
<th>Industry</th>
<th>Academia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism will achieve its purpose</td>
<td>Yes 6</td>
<td>Yes 7</td>
<td>Yes 6</td>
<td>Yes 2</td>
</tr>
<tr>
<td></td>
<td>No 1</td>
<td>No 2</td>
<td>No 1</td>
<td>No 2</td>
</tr>
<tr>
<td></td>
<td>No answer 1</td>
<td>No answer 1</td>
<td>No answer 0</td>
<td>No answer 1</td>
</tr>
<tr>
<td>Mechanism will improve patients’ health status</td>
<td>Yes 7</td>
<td>Yes 7</td>
<td>Yes 6</td>
<td>No 4</td>
</tr>
<tr>
<td></td>
<td>No 0</td>
<td>No 1</td>
<td>No 0</td>
<td>Yes 4</td>
</tr>
<tr>
<td></td>
<td>No answer 1</td>
<td>No answer 2</td>
<td>No answer 0</td>
<td>No answer 1</td>
</tr>
<tr>
<td>Mechanism is possible to implement</td>
<td>Yes 6</td>
<td>No 2</td>
<td>No 7</td>
<td>No 2</td>
</tr>
<tr>
<td></td>
<td>No 2</td>
<td>No 7</td>
<td>No 3</td>
<td>No 2</td>
</tr>
<tr>
<td></td>
<td>No answer 0</td>
<td>No answer 1</td>
<td>No answer 0</td>
<td>No answer 2</td>
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All stakeholders strive for fewer uncertainties in the health care
system. Risk-sharing is a good idea, but not so simple to imple-
ment. We need to initiate immediately a dialogue process be-
tween all stakeholders. With good willing of all parties, and if
all parties will recognize that the proposed scheme fits with their
interests, risk-sharing will be applicable. (Health plans 3)

Discussion

We explored the views and concerns of the major stakeholders in
the Israeli health care system toward the implementation of a
conceptual financial risk-sharing scheme. In Israel, the PNAC will
usually recommend including new technologies in the NLHS only
if the evidence on efficacy and effectiveness is sufficient and con-
vincing. The major uncertainty in the NLHS update decision pro-
cess relates to the actual budget required for reimbursing the
listed technologies. Therefore, our proposed risk-sharing frame-
work does not deal with the clinical performance of a specific
technology, but rather with the total budget utilized, once covered
and reimbursed, and its correspondence with the predefined allo-
cated budget, determined by early budget-impact estimates.

Despite the growing use of risk-sharing arrangements and
their intuitive appeal to policymakers and health care payers,
there are only few academic publications on this topic. Recently,
Stafinski et al. [4] reviewed the literature on stakeholders’ opinions
on perceived advantages and disadvantages of risk-sharing and
“access with evidence development” schemes. They found that all
stakeholders (e.g., technology sponsors, patients, providers, and
payers) seemed to share the view that these schemes offer the
potential to facilitate patient access to promising new technologies
while ensuring effective use of scarce health care resources, al-
though this information was sparse and mainly represented “gray”
literature publications. To the best of our knowledge, stakeholders’
opinions on using risk-sharing as a tool for improving the accuracy of
budget-impact estimations have not been examined yet.

In our study, we found that most interviewees agreed that the
conceptual risk-sharing scheme would indeed improve early bud-
get estimates. All participants from health plans and most tech-
nology sponsors supported the proposed risk-sharing agreement.
The health plans’ support was quite obvious to most participants
because health plans are currently the only stakeholders who bear
the financial risk in the case of overuse of newly listed technolo-
gies. On the other hand, the technology sponsors’ support of the
proposed scheme was not apparent to many of the other partici-
pants, because of the potential loss of profits from the part of the
industry. The main sponsors’ considerations in supporting the
scheme were related to their desire to enhance their chances of ob-
taining market access for their products, which would usually out-
weigh the financial risk inherent in the risk-sharing mechanism.

Recent developments in the process of updating the NLHS in
Israel suggest that MOH, MOF, and health plans officials, as well as
technology sponsors, became supportive toward exploring the ac-
ual feasibility of budget-impact risk-sharing agreements. In prep-
stakeholders assume that risk sharing will, in fact, improve the accuracy of early budget-impact estimates and that although intuitively technology sponsors should object to risk-sharing, in reality they would generally support such a budget-impact scheme.

It should be emphasized that when implementing such a scheme, stakeholders’ acceptance of the model and their provided budget-impact estimates would actually depend on the numerical parameters and tolerance levels imposed in the mechanism. In this regard, Zaric and O’Brein [25] suggest that even with a risk-sharing scheme in place, it may be optimal for the budget-impact analysis provider to over- or underestimate total drug expenditures; they have shown that manufacturer’s optimal projections vary in the unit price, the unit cost, and the rebate proportion. Further studies that will bring to light the optimal behaviors of parties engaged in risk-sharing agreements are warranted.

As revealed in our interviews, the success of implementing a risk-sharing mechanism depends mainly on a high grade of trust and collaboration among all stakeholders. Although all parties strive for fewer uncertainties in the health care system, when introducing a risk-sharing scheme it is essential to prove to all parties that the proposed framework is a win-win arrangement. If all stakeholders will recognize that the proposed scheme fits with their interests, risk-sharing would be applicable.

Conclusions

Uncertainties regarding the total financial consequences associated with listing a technology on a national or a health plan for- mulary exist in all health care systems. While the listing makes a drug available for prescribing, it cannot determine the total demand because treatment recommendations are made and induced almost solely by practicing clinicians. Implementing a risk-sharing mechanism on the budget impact, as suggested in our study, may help in reducing these uncertainties.

Risk-sharing schemes will most likely continue to emerge in many health care systems. The success of implementing a risk-sharing mechanism depends mainly on its perception as a win-win situation for all stakeholders involved. The challenges pointed out by participants in this study regarding the adoption of a risk-sharing scheme may be relevant to other health care systems and are essential when considering the plausibility for its implementation. We recommend that decision-makers consider the different stakeholders’ perceptions exposed in our study that, in many cases, could be relevant when implementing similar or different types of risk-sharing schemes in other health care systems.

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Supplemental Materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at doi:10.1016/j.jval.2012.01.007 or, if a hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

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