BIOCOMPATIBLE PERITONEAL DIALYSIS (PD) SOLUTION
Executive Summary
[Adapted from the report by MAHARITA AB RAHMAN]

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Background
End stage renal disease (ESRD) is defined as irreversible decline in kidney function, which is severe enough to be fatal in the absence of dialysis or transplantation. In Malaysia, a population-based study in 2011 reported that 9.1% of Malaysians were found to have chronic kidney dialysis (CKD). Breakdown of the prevalence by stages were as follows; stage 1, 4.16%; stage 2, 2.0%; stage 3, 2.26%; stage 4, 0.24%; and stage 5, 0.36%.

In 2016, the most common type of renal replacement therapy (RRT) in Malaysia was haemodialysis (HD), followed by peritoneal dialysis (PD)and renal transplantation. Between 2007 and 2016, the prevalence of HD and PD in Malaysia increased 2.3 times and 2.5 times, respectively. The annual death rate of patients on dialysis in 2015 was 13.4% which the annual death rate among PD patients was 16.9% and 13% among HD patients.

Peritoneal dialysis is a home based therapy which a patient is required to perform three to four PD exchanges per day. The PD solution or dialysate play crucial role in dialysis. The dialysate solution is a nonsterile aqueous electrolyte solution that is similar to the normal levels of electrolytes found in extracellular fluid with the exception of the buffer bicarbonate and potassium. Dialysate solution is almost an isotonic solution, with the usual osmolality of approximately 300 ± 20 miliosmoles per liter (mOsm/L). The PD solutions can be divided into conventional PD solutions and novel solutions with more biocompatible characteristics (such as neutral-pH, low glucose degradation products -GDPs solutions including icodextrin). Conventional PD solutions are characterized by several undesirable characteristics which result in adverse clinical outcomes.

Thus, there was a request from the National Advisor of Nephrologist to look at the potential of expanding PD using biocompatible PD solution for sake of the patient's safety as well as cost-saving compared to conventional PD solution.

Objectives
To assess the efficacy or effectiveness, safety, and cost-effectiveness of biocompatible PD solution

Methods
Electronic databases were searched through Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1948 to present, EBM Reviews-Cochrane Database of Systematic review, EBM Reviews-Cochrane Methodology Register of Controlled Trials, EBM Reviews-Health Technology Assessment, EBM Reviews-NHS Economic Evaluation Database, and Embase 1996 to 2nd March 2020. Searches were also run in PubMed, FDA website and INAHTA for any published reports. Study was limited to 2000 onwards. Google and Google Scholar were also used to search for additional web-based materials and information about the technology. Besides, additional articles were also search by reviewing the references of retrieval articles.

Results and Conclusions
Nine studies were included in the report; all 9 studies were on the effectiveness and safety. No economic evaluation studies retrieved specifically on biocompatible PD solution

Efficacy / Effectiveness
Neutral pH, low GDP PD solution was better compared to conventional PD solution in improving the residual renal function (RRF) or urine volume. However, for

Icodextrin, the RRF showed no significant difference compared to conventional PD solution in SR and MA but a little increase and better improvement in another studies after six months. Another main outcome was on cardiovascular events, the Icodextrin solution showed an improvement in coronary heart failure (CHF). The cumulative incident CHF was lower in Icodextrin users than non-users. Besides, the CHF incidence rate also greater in diabetic patient without using Icodextrin subgroups than in diabetic patient who were using Icodextrin PD solution. The hazard ratio of CHF in diabetes patient on Icodextrin also lower compared to diabetes patient without Icodextrin PD solution. On the other hand, Icodextrin showed no significant difference in any changes in cardiovascular structure and function, however, this finding requires further study.

On the other hand, for other outcomes the evidence varied and most of the findings was at low certainty evidence. The biocompatible or neutral pH, low GDP PD solution showed lower peritoneal ultrafiltration compared to conventional PD solution after four hours of PD, minimal changes in peritoneal membrane and MIA syndrome (chronic inflammation, malnutrition and atherosclerosis). However, for Icodextrin, the included study showed there was an increase trend but not significant in ultrafiltration capacity. There was also no significant difference in peritoneal small solute clearance, peritonitis rate and patient survival between biocompatible or neutral pH, low GDP PD solution and Icodextrin. Meanwhile, findings for inflow pain and hospitalisation was uncertain in all biocompatible PD solutions.

Safety
Safety issue for both neutral pH, low GDP and Icodextrin PD solution was uncertain.

Cost/Cost-Effectiveness Analysis
No economic evaluation comparing biocompatible PD solution and conventional PD solution retrieved. The economic evaluation papers retrieved showed that peritoneal dialysis was cost saving over haemodialysis.

Organizational
The above review showed that there was no difference to death-censored technique failure between neutral pH, low GDP PD solution and conventional PD solution. Meanwhile for Icodextrin, the technique failure was uncertain except one study showed that non-compliance in Icodextrin group was significantly lower that non-Icodextrin group